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PRINCIPAL INVESTIGATOR: Timothy J. Whelan

CONTRACTING ORGANIZATION: McMaster University
Hamilton, Ontario L8N 3Z5 Canada

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Timothy J. Whelan

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
McMaster University
Hamilton, Ontario L8N 3Z5 Canada

E-Mail: tim.whelan@hrcc.on.ca

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Women with breast cancer have increasingly indicated a desire for more information about their disease and the need to be involved in making decisions about their care. We have developed two decision aids called Decision Boards (DB) to help clinicians inform patients about their treatment options. One DB involves the surgical decision between mastectomy and lumpectomy plus radiation (DECIDE-S); the other involves the decision between chemotherapy options for the treatment of node-negative and early node-positive breast cancer (DECIDE-C). The objectives of this study are to; i) develop computer based versions of both the DB for the surgical treatment of breast cancer and the DB for chemotherapy for node-negative and early node-positive breast cancer; and ii) to compare the relative effectiveness of the computer-based versions and paper versions with the standard versions of the DB for women with early breast cancer. In the fourth year, there were a number of key accomplishments. We extended the eligibility criteria to include node-positive patients in the DECIDE-C trial; revised the DECIDE-C and DECIDE-S take-home versions; conducted an extensive revision of the DECIDE-C computer-based version; and revised the DECIDE-S computer-based version. We have accrued 25 patients to the DECIDE-C study and expect to start the DECIDE-S study on November 15, 2002.

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## Table of Contents

## Introduction

Since our last report, we have applied for a no-cost extension of the study to complete the randomized trial. While developing the computer version of the Decision Board (DB) and in other studies, we identified that physicians and patients found a paper version of the decision board easy to use. Thus, we added a third arm to the trial such that we will now compare the standard plastic poster sized version of the DB, the computer-based version, and a paper version, both for the chemotherapy decision aid (DECIDE-C) and the surgical decision aid (DECIDE-S). The randomized trial is now open and is accruing patients as expected. We are just in the process now of opening up the trial to surgeons to compare the different versions of the surgery instrument. The plan is to complete accrual to the study over the next 16 months. We will submit a final report for May 2004.

## Body

Progress made towards meeting objectives since the last review is outlined below. The randomized trial of the chemotherapy version of the DB (DECIDE-C) has started and is running smoothly. The randomized trial of the surgical version of the DB (DECIDE-S) is scheduled to start November 15, 2002.

**Task 1: Development of Computer-based Version of Decision Boards and Updating the Standard Versions of the Decision Boards Currently Used at the HRCC and Outlying Communities: Completed.**

One development this year was extending the eligibility criteria to include node-positive patients in the DECIDE-C trial. It was determined that there were still a significant number of node-positive patients being seen at the Hamilton Regional Cancer Centre (HRCC) who were eligible for DECIDE-C and were not being approached about ongoing therapeutic clinical trials. All three versions of the DB had to be revised to incorporate the necessary information pertaining to probabilities of recurrence for node-positive patients entering the trial.

As a result of adding node-positive patients back into the trial, baseline risks of recurrent disease were determined from previous randomized trials[1] and benefits of chemotherapy from the Early Breast Cancer Trialists Collaborative Group meta analysis[2,3] (Appendix 1). Two versions of the DB do not show outcome probabilities due to concern by several physicians that some patients may not like to see numbers relating to their chances of

recurrence. In these versions, discussion of the treatment options occurs without discussion of the risk of recurrence.

A second development was the revision of the DECIDE-C take-home brochures. Two types of take-home brochures are available for the DECIDE-C study, the Standard version (Appendix 2) and the Computer version (Appendix 3). The paper take-home version of the DB also serves as the stand-alone instrument for the new third arm of the study.

The third development was an extensive update to the computer-based version of DECIDE-C. These revisions were: (i) Making the DB more personalized for the patient by adding additional information to the opening screen that the physician must enter to ensure that the appropriate version (1-26) of the DB is shown to the patient. The information entered into the computer is specific to the patient's tumour and includes: menopausal status, estrogen receptor status, number of positive lymph nodes, tumour size, tumour grade and if lymphovascular invasion was present or absent. As the physician enters this information into the computer in front of the patient, it allows the patient to realize that the information being shown to her is personalized to her specific tumour and also allows the patient to ask questions about each of the tumour features. (ii) A timing feature was also added to allow the collection of the length of time that each panel of the DB is opened, thus allowing us to determine how much time was spent discussing each part of the DB.

A fourth development was the refinement of the computer version for the DECIDE-S study. Although the computer version of the surgical DB had been developed and pilot tested previously, some aspects were enhanced to make it comparable to the DECIDE-C

computer version. Some items that were enhanced were: (i) the introduction screens automatically pop up when the physician opens up the correct version of the DB, (ii) features were added to allow easier movement through the decision board and (iii) the timing feature was also added.

A fifth development was the revision of the DECIDE-S take-home brochures so that they were comparable to the DECIDE-C take-home brochures (Appendix 4 and 5).

**Task 2: Start up of the RCT. Development of Operations Manuals, Data Forms, Training of Clinicians to use Computer-Based Versions: Completed.**

One major development this year was developing and adding a new paper version of the DB as a treatment arm in the trial. When physicians on other Supportive Cancer Care Research Unit DB trials were interviewed it was found that some physicians were continuing to use the take-home brochure with patients in their every day practice after the trial was completed. Physicians found that the paper version of the DB was easy and convenient to use. They could present the information to the patient, write on the paper version, and give it to the patient to take the brochure home to study and make a decision about treatment. The new paper version, which will be evaluated as a separate arm of the trial, is essentially the Standard take-home version of the DB alone. A take-home version of the DB is normally given to women after the options have been discussed with the standard form of the board. The new third arm of the study will be the use of the paper take-home version alone. Thus patients will be randomized to one of three arms:

1. Standard version (plastic poster size) of the DB plus a paper take-home version following the discussion.
2. Computer version of the DB plus a computer take-home version (either a disk or a paper version of the computer instrument for those who do not have access to a computer).
3. A simple paper version of the DB, which the patient can then take-home with her.

The study will evaluate which instrument is more effective in terms of improving patient comprehension and satisfaction.

The Operations Manuals for both the DECIDE-C and DECIDE-S studies were developed last year and updated to include changes in the number of treatment arms and versions of the chemotherapy DB.

To ensure that the physicians knew how to use all three versions of the DECIDE-C DB, the Research Coordinator met with each of the six Medical Oncologists at the HRCC individually to review each DB and its proper use. A presentation by the Principle Investigator at the Breast Disease Site Group meeting at the HRCC ensured that residents, clinical fellows and nurses were also familiar with the study.

All Case Report Forms (CRFs) were finalized and minor changes have been made since the commencement of the trial.

Prior to starting the DECIDE-S study, the Research Coordinator will meet with each surgeon individually and review the proper use of each version of the DB and also how to run the study properly in their office. The Research Coordinator will also meet with the receptionist or nurse at each office to discuss how the study will work and his/her part in the process.

**Task 3: Patient Recruitment and Data Collection: In Progress.**

Patient recruitment to DECIDE-C started on April 29, 2002 with the first patient randomized on May 8, 2002. There are currently 25 patients randomized to the trial. We expect to accrue 100 patients to DECIDE-C by December 31, 2003. Six Medical Oncologists at the HRCC are currently actively recruiting patients to the trial. We have decided at this point not to approach other centres to participate in the trial since accrual targets are adequate. If accrual does not remain at target we will consider approaching other centres.

The DECIDE-S randomized trial is scheduled to be open for recruitment on November 15, 2002. It is planned to start the study at two local surgeon's offices that have experience using the DB and participating in clinical trials. Once all of the "bugs" are worked out in these two surgeon's offices the study will start at the remaining six community surgeon's offices. The surgeons have relatively large breast cancer practices and we expect to recruit 100 patients in 13 months to the DECIDE-S study.

Since our last report we have received a 16-month no-cost extension to complete the RCT portion of the study. We expect to finish accrual by December 2003 with a final report by the beginning of May 2004.

**Task 4: Data Entry and Analyses: In Progress.**

Two databases were created for the DECIDE-C study. The study database was set up to hold the information collected on the CRFs. Quality assurance programs will be written to ensure the quality of the data. Data entry is up to date on the study. A second database, called a Trial Management System (TMS) was designed to help keep track of patient visits and the timeliness of the collection of the CRFs. The TMS generates a number of monthly reports that indicate how the trial is doing in terms of patient accrual, CRF completion, overdue assessments, upcoming visits, and data entry (Appendix 6). These reports help to ensure that the trial runs smoothly, no visits are missed, and all CRFs are collected in a timely fashion.

## Key Research Accomplishments

### Year 4

- Start-up of the randomized control trial of DECIDE-C
- Added paper version as a third treatment arm
- Enabled node-positive patients to enter (if not competing with other clinical trials)
- Added more personalized features to DECIDE-C board
- Revised the DECIDE-S version of the decision board based on feedback from the DECIDE-C version
- Created the Study Database and started data entry
- Created the Trial Management Database

### Year 3

- Updated the standard version of the node-negative Decision Board
- Revised the computer version of the node-negative Decision Board
- Field testing of the computer version of the node-negative Decision Board was completed
- Completed field testing of the computer version of the node-negative Decision Board

### Year 2

- Completed field testing of the computerized version of the surgery Decision Board
- Developed prototype of the computerized version of the node-negative Decision Board
- Completed field testing of the standard version of the node positive Decision Board
- Developed a prototype of the computerized version of the node-positive Decision Board
- Field testing of the computerized version of the node-positive Decision Board
- Field testing of the computerized version of the node-negative Decision Board

**Year 1**

- Completed a review of the literature and updated the standard version of the surgery Decision Board
- Completed a review of the literature and updated the standard version of the node-positive Decision Board
- Completed a review of the literature and updated the standard version of node-positive Decision Board
- Developed the computerized version of the surgery Decision Board

## Reportable Outcomes

### Grants received:

Canadian Research Chair in Health Services Research in Cancer, 2000-2006.

### Grants submitted:

Ellis P, **Whelan T**, Charles C. Physician and patient characteristics that promote shared decision-making in the oncology consultation. Submitted to the Canadian Institutes for Health Research, September 2002.

### Publications:

### Peer Reviewed:

Levine ML, **Whelan TJ**. Decision-making process – communicating risk/benefits: is there an ideal technique? Journal of the National Cancer Institute 2001; 30:143-145.

Charles C, Gafni A, **Whelan T**. How to improve communication between doctors and patients. BMJ 2000; 320:1220-1221.

**Whelan T,** Gafni A, Charles C. Lessons learned from the Decision Board: A unique and evolving decision aid. Health Expectations 2000; 3:69-76.

Charles C, Gafni A, **Whelan T**. International Conference on Treatment Decision-Making in the Clinical Encounter. Editorial: Special Conference Issue. Health Expectations 2000; 3: 1-5.

### Other Publications:

**Whelan T**, O'Brien MA, Villasis-Keever M, Robinson P, Skye A, Gafni A, et al. Impact of Cancer-Related Decision Aids. Evidence Report/Technology Assessment, Number 46, Agency for Healthcare Research and Quality, July 2002.

### Journal articles submitted for publication:

Charles CA**, Whelan T**, Gafni A, Farrell S, Willan A. The meaning of shared decision-making to physicians treating women with breast cancer. Submitted to the Journal of Clinical Oncology, 2002.

**Abstracts:**

O'Brien MA, **Whelan T**, Villasis-Keever M, Robinson P, Skye A, Gafni A, Brouwers M, Baldassarre F, Gauld M, Willan A. Impact of cancer-related decision aids: A systematic review. Presented at the International Conference on Communication in Healthcare, Warwich, UK, September 2002.

O'Brien MA, **Whelan T**, Villasis-Keever M, Robinson P, Skye A, Gafni A, Brouwers M, Baldassarre F, Gauld M, Willan A. Impact of cancer-related decision aids: A systematic review. Poster presentation at ASCO Annual Meeting, Orlando, FL, May 18-22, 2002.

**Presentations:**

**Whelan T.** Shared Decision-Making: What Is It and How Can We Make It Happen? 44th Annual Meeting of the American Society for Therapeutic Radiology and Oncology, New Orleans, LA, October 5-10, 2002.

**Whelan T.** Accelerated treatment with increased fractionation for breast irradiation: The use of a decision board for breast cancer treatment decisions: Current and proposed trials of local therapy. 19th Annual Miami Breast Cancer Conference, Miami Beach, FL, February 27-March 2, 2002.

**Whelan T.** Decision-Making in Oncology: Models or Decision Aids. Society of Clinical Oncologists (ASCO) Conference, Miami, FL, January 21-24, 2002.

**Whelan TJ**, Sawka C, Levine M, Gafni LA, Reyno L, Willan A, Dent S, Abu-Zahra H, Chouinard E, Tozer R, Pritchard K, O'Connor A, Bodendorfer I. A randomized trial of a decision aid for the use of adjuvant chemotherapy in women with node-negative breast cancer. Proceedings of the American Society Clinical Oncology, Journal Clinical Oncology 2001; 20: 237a.

**Whelan TJ**, Sawka C, Levine M, Gafni LA, Reyno L, Willan A, Dent S, Abu-Zahra H, Chouinard E, Tozer R, Pritchard K, O'Connor A, Bodendorfer I. Randomized trial of the decision board for the use of adjuvant chemotherapy in women with node-negative breast cancer. Presented at the Shared Decision-making in Health Care Summer School, Oxford, England, July 11-13, 2001.

**Whelan T**, Mirsky D, Levine M, Gafni A, Willan A, Sanders K, Reid S, Rush B. Randomized trial of the Decision Board for breast cancer surgery. Presented at the Canadian Breast Cancer Research Initiative (CBCRI) 2nd Scientific Conference "Reasons for Hope", Quebec City, PQ, May 3-5, 2001.

**Whelan T**, Bodendorfer I, Levine M, Gafni A, Sebaldt R, Julian J, Tozer R, Reid S, Sanders K, Lewis MJ. Development and evaluation of computer-based versions of the Decision Board for early breast cancer. Presented at the CBCRI 2nd Scientific Conference "Reasons for Hope", Quebec City, PQ, May 3-5, 2001.

**Whelan TJ**, Sebaldt R, Gafni A, Levine M, Bodendorfer I, Tozer R, Sanders K, Reid S. Computer-based versions of the Decision Board: An interactive decision aid for early breast cancer. Presented at the Department of Defence, U.S. Army Medical Research and Materiel Command, "Era of Hope Meeting", Atlanta, GA, June 8-12, 2000.

**Invited Presentations:**

**Whelan T.** Helping women make informed decisions through the use of decision aids in breast cancer. Breast Cancer Awareness Day, Halifax, NS, October 31, 2001.

**Whelan T.** Treatment decision making. Is there an ideal technique? ASTRO Outcomes Meeting, Toronto, Ontario, June 2, 2001

**Whelan T.** Shared decision making in breast cancer? BC Cancer Agency, Vancouver, BC, March 30, 2001.

**Whelan T.** Decision making in breast cancer. 5th Annual Atlantic Canada Oncology Group Winter Symposium, Corner Brook, NF, February 8-11, 2001.

## Conclusions

The DECIDE-C randomized trial accrual is well on its way to meeting the target of 100 patients with 25 patients currently randomized, while the DECIDE-S trial is scheduled to start on November 15, 2002.

The study now includes three arms with the addition of a paper version for both the chemotherapy and surgery DBs. Therefore, patients will be randomized to the Standard DB, Computer DB or the Paper DB. The paper version was added because physicians found the take-home version of the DB a convenient way to present the chemotherapy and surgical options to patients outside of a clinical trial.

It was discovered that some node-positive breast cancer patients at the HRCC were not being offered therapeutic clinic trials and were therefore, still eligible to enter into the DECIDE-C study. As a result, versions of the DB were created to allow these patients to enter into our trial.

Both a study database and a management database were set up for the DECIDE-C study, with data entry started and up to date.

## References


1. Clark RM, Whelan T, Levine M, Roberts R, Willan A, McCulloch, et al. Randomized Clinical Trial of breast irradiation following lumpectomy and axillary dissection for node-negative breast cancer. Journal of the National Cancer Institute 1996; 88: 1659-1664.

2. Early Breast Cancer Trialists Collaborative Group. Polychemotherapy for early breast cancer: an overview of the randomised trials. The Lancet 1998; 352: 930-942.

3. Early Breast Cancer Trialists Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomised trials. The Lancet 1998; 351: 1451-1467.

## Appendices

**Appendix 1.** Versions of DECIDE-C Decision Board

**Appendix 2.** DECIDE-C Standard Take-Home Example

**Appendix 3.** DECIDE-C Computer Take-Home Example

**Appendix 4.** DECIDE-S Standard Take-Home Example

**Appendix 5.** DECIDE-S Computer Take-Home Example

**Appendix 6.** Trial Management Reports

# Appendix 1

## Versions of DECIDE-C Decision Board

*(table showing disease criteria for each version)*

# INDEX

| NODE NEGATIVE | ER Positive | | | |
|---|---|---|---|---|
| **Description of Disease** | **Menopausal status** | **Tamoxifen Only** | **Tamoxifen and Chemo** | **Decision Board Version** |
| < 1cm, and one of (GIII or LVI Present) or 1 - < 2cm, GII and LVI Absent or ≥ 2 cm - < 3 cm, GI or GII, and LVI Absent | Pre-menopausal | 85 / 15 | 90 / 10 | 1 |
| | Post-menopausal | 85 / 15 | 90 / 10 | 2 |
| ≥ 3 cm (GI or GII, and LVI Absent) or 1 - < 2 cm and one of (GIII or LVI Present) | Pre-menopausal | 75 / 25 | 85 / 15 | 3 |
| | Post-menopausal | 75 / 25 | 80 / 20 | |
| ≥ 2 cm and one of (GIII or LVI Present) | Pre-menopausal | 65 / 35 | 75 / 25 | |
| | Post-menopausal | 65 / 35 | 75 / 25 | |

| NODE NEGATIVE | ER Negative | | | |
|---|---|---|---|---|
| <1cm | Pre-menopausal | 80 / 20 | 85 / 15 | |
| | Post-menopausal | 80 / 20 | 85 / 15 | |
| 1-<2cm | Pre-menopausal | 65 / 35 | 75 / 25 | |
| | Post-menopausal | 65 / 35 | 70 / 30 | |
| ≥2cm | Pre-menopausal | 50 / 50 | 65 / 35 | |
| | Post-menopausal | 50 / 50 | 55 / 45 | |

* Node Negative (< 1 cm, ER +, GI or GII, LVI absent), and (1 - < 2cm, ER +, GI, LVI Absent) tumours are not included)

| NODE POSITIVE | ER Positive | | | |
|---|---|---|---|---|
| 1 - 3 positive lymph nodes | Pre-menopausal | 65 / 35 | 75 / 25 | |
| | Post-menopausal | 65 / 35 | 70 / 30 | 14 |
| 4 - 9 positive lymph nodes | Pre-menopausal | 55 / 45 | 65 / 35 | 15 |
| | Post-menopausal | 40 / 60 | 55 / 45 | [illegible] |
| ≥ 10 positive lymph nodes | Pre-menopausal | 40 / 60 | 55 / 45 | 17 |
| | Post-menopausal | 40 / 60 | 45 / 55 | [illegible] |

| NODE POSITIVE | ER Negative | | | |
|---|---|---|---|---|
| 1 - 3 positive lymph nodes | Pre-menopausal | 50 / 50 | 65 / 35 | |
| | Post-menopausal | 50 / 50 | 55 / 45 | |
| 4 - 9 positive lymph nodes | Pre-menopausal | 35 / 65 | 50 / 50 | |
| | Post-menopausal | 35 / 65 | 45 / 55 | |
| ≥ 10 positive lymph nodes | Pre-menopausal | 20 / 80 | 35 / 65 | |
| | Post-menopausal | 20 / 80 | 30 / 70 | |

| NO OUTCOME PROBABILITIES | | | | |
|---|---|---|---|---|
| No Outcome Probability Versions | ER Positive | -- | -- | |
| | ER Negative | -- | -- | |

# Appendix 2

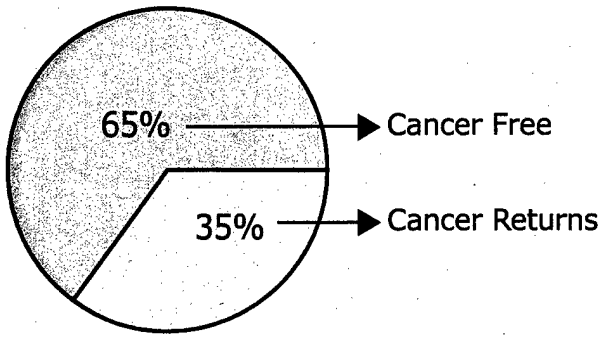
## DECIDE-C Standard Take-Home Example

*(Example of Version 3 of 26 different versions)*

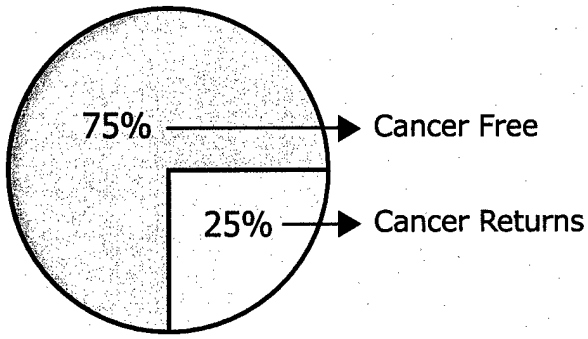
# DECISION BOARD

## INTRODUCTION

- Recently, you had surgery for cancer of the breast. The cancer was removed by either a lumpectomy or a mastectomy.
- Although the cancer was removed, it may still come back as a local recurrence (breast or chest wall) or a distant recurrence (e.g., liver, lung, bone).
- Unfortunately, cancer that comes back as a distant recurrence can be treated, but cannot be cured.
- Tamoxifen (pill for 5 years) will reduce your chances of cancer coming back.




Without Tamoxifen or chemotherapy




With Tamoxifen but no chemotherapy

- Scientific studies have shown that chemotherapy when taken in addition to Tamoxifen may further prevent the cancer from returning.
- The Decision Board is a visual aid to help present information about chemotherapy and to help you take part in deciding about treatment.
- Although there is some benefit from chemotherapy, there are also side effects. Therefore, your participation in the decision about whether or not you receive chemotherapy is important. If you choose to receive chemotherapy, you will be offered Tamoxifen after chemotherapy is completed.

**Version 3, April 2002**

# TREATMENT CHOICES

## NO CHEMO

### What happens if I decide not to have chemotherapy?

- followed at Cancer Centre on a regular basis
  - physical examination
  - blood work (at some visits)
- yearly mammogram
- other tests, if doctor feels they are necessary

## CHEMOTHERAPY

### What is chemotherapy?

- a treatment program using drugs that fight cancer cells

### How is chemotherapy given?

- combination of 2 or 3 drugs are given together by:
  - injections (at Cancer Centre) and pills (taken at home), or injections only (at Cancer Centre)
- drugs are given in a "treatment cycle"
- each treatment cycle lasts 3 to 4 weeks
- during each treatment cycle there are 2 to 3 weeks when no chemotherapy is given
- each treatment cycle is repeated 4 to 6 times
- takes 3 to 6 months to finish all treatment cycles

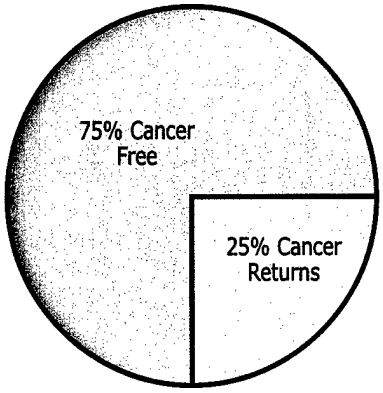
### What happens after finishing chemotherapy?

- followed at Cancer Centre on a regular basis
  - physical examination
  - blood work (at some visits)
- yearly mammogram
- other tests, if doctor feels they are necessary

## SIDE EFFECTS

## OUTCOME

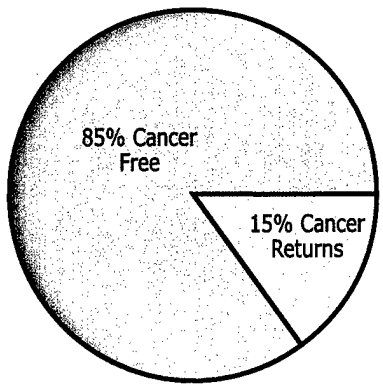
- No chemotherapy side effects




### What are the Side Effects of Chemotherapy?

**There are a number of possible side effects with any type of chemotherapy. They are:**

- Loss of energy and tiredness
- Loss of hair or thinning of hair over the entire body
- Stomach upset (nausea) and vomiting
- Mouth sores (tenderness)
- Weight gain
- Sad or unhappy moods
- Early menopause
- Diarrhea or constipation
- Low blood counts
- Infection which may require hospitalization
- Blood clots
- Leukemia (very rarely)
- Heart damage (very rarely)



# OUTCOME

## CANCER FREE

- All tests and examinations in the coming 10 years show that you are free of cancer.
- You will continue to be followed on a regular basis.
- Even though all the examinations show you are cancer free, from time to time, you may worry about the cancer coming back.

## CANCER RETURNS

- Breast cancer may come back in the next 10 years.
- Breast cancer can come back in the same breast or on the chest wall (local recurrence).
- When cancer returns in the breast or on the chest wall, it is often seen as a small painless lump. It is usually removed by a surgeon.
- Breast cancer can come back in other parts of the body, such as the bone, liver or lung (distant recurrence).
- Many women whose cancer comes back in other parts of the body receive further treatment: chemotherapy, hormonal therapies, radiation therapy and/or pain medication.
- Unfortunately, a patient whose breast cancer comes back in other parts of the body can be treated but cannot be cured.

# MENOPAUSE

- For women who have not reached menopause, treatments for breast cancer may cause a loss of menstrual periods.
- Younger women, those in their 20's and early 30's, are more likely to experience irregular periods or a temporary loss of periods during treatment. Their regular periods are likely to start again after finishing chemotherapy and they will continue to be fertile. Women over the age of 40 are more likely to experience a permanent loss of periods.
- Hormone replacement therapy, a treatment often given to relieve menopausal symptoms, is not recommended for women with breast cancer. At this point, we do not know enough about how hormone replacement therapy might affect the cancer.

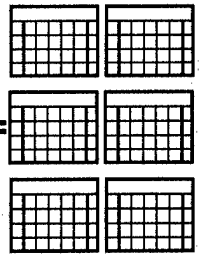
*Remember there are two different types of chemotherapy treatment for your type of cancer. The two types of chemotherapy are described on the following pages. . .*

# TREATMENT CHOICES

**C M F**

## CMF Treatment Cycle

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---|---|---|---|---|---|---|---|
| Week 1 |  |  |  |  |  |  |  |
| Week 2 |  |  |  |  |  |  |  |
| Week 3 | ← | | No Chemotherapy | | | | → |
| Week 4 | ← | | No Chemotherapy | | | | → |

X 6 = 

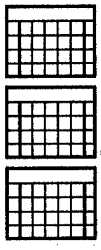
**6 months**

- "treatment cycle" lasts **4 weeks**
- 3 chemotherapy drugs:
  - **Cyclophosphamide** (pills taken by mouth)
    - every day for first 2 weeks of every treatment cycle
  - **Methotrexate and Fluorouracil** (given intravenously)
    - two times – Day 1 of first week and day 1 of second week in each treatment cycle
- takes about 20 minutes to receive intravenous drugs
- treatment cycle repeated 6 times for a total of **6 months**

**A C**

## AC Treatment Cycle

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---|---|---|---|---|---|---|---|
| Week 1 |  | ← | No Chemotherapy | | | | → |
| Week 2 | ← | | No Chemotherapy | | | | → |
| Week 3 | ← | | No Chemotherapy | | | | → |

X 4 = 

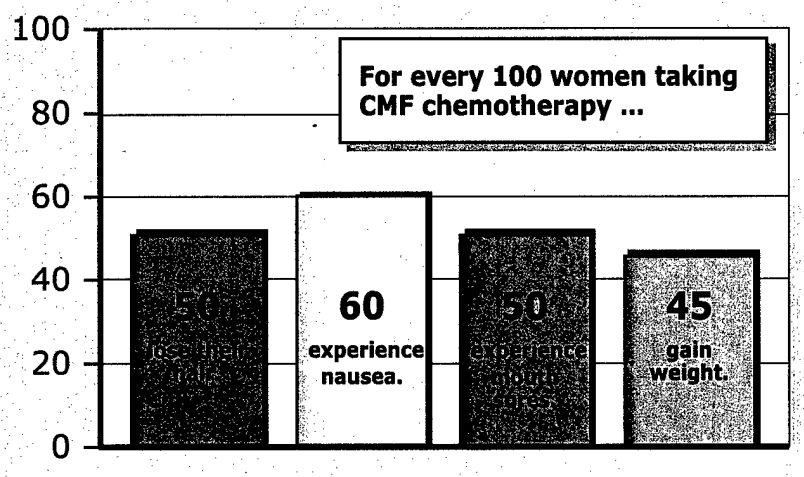
**3 months**

- "treatment cycle" lasts **3 weeks**
- 2 chemotherapy drugs:
  - **Adriamycin and Cyclophosphamide**
    - given intravenously
    - one time only - first day of each treatment cycle
- takes about 60 minutes to receive intravenous drugs
- treatment cycle repeated 4 times for a total of **3 months**

## SIDE EFFECTS

## OUTCOME

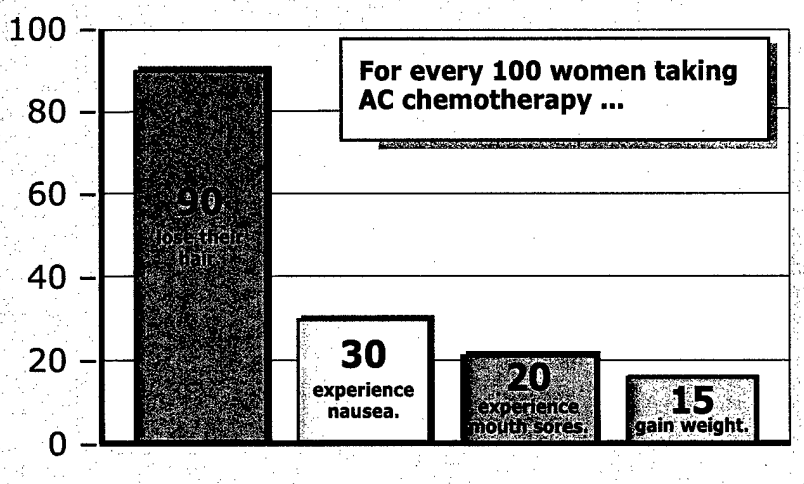
### Side Effects of CMF Chemotherapy




- With CMF, very few women will experience serious side effects such as infection (10 in 1000), leukemia (2 in 1000) and heart damage (virtually none).

The chances of remaining cancer free are the **SAME** with either type of chemotherapy

### Side Effects of AC Chemotherapy




- With AC, very few women will experience serious side effects such as infection (20 in 1000), leukemia (4 in 1000) and heart damage (2 in 1000).

# SUMMARY

- We have discussed your choices of no chemotherapy or chemotherapy, the side effects associated with each choice and the chance of cancer returning for each choice.
- Chemotherapy reduces the chances of cancer returning but is associated with side effects.
- We have discussed 2 types of chemotherapy, CMF and AC. Each reduces the chance of cancer returning by the same amount, but they have different side effects and lengths of treatment.
- Please keep in mind that we can predict what will happen to groups of women but we cannot predict what will happen to you as an individual.
- Also remember that as you talk with others who have experienced cancer or when you see the experience of others on television or in movies, your experience with side effects such as nausea or weight gain may not be the same as it was for them.

## Questions for your Doctor or Nurse:

_____

_____

_____

_____

_____

_____

_____

For additional Information contact:

**Supportive Cancer Care Research Unit**
**Hamilton Regional Cancer Centre**
**699 Concession Street, Level 3**
**Hamilton, ON, Canada L8V 5C2**
**Tel: 905.387.9711, ext. 64510**

# Appendix 3

## DECIDE-C Computer Take-Home Example

*(Example of Version 3 of 26 different versions)*

# DECISION BOARD

## for breast cancer chemotherapy

Version 3

Supportive Cancer Care Research Unit
Hamilton Regional Cancer Centre

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

Introduction | Menopause and Breast Cancer | Summary

No Chemo

Chemo

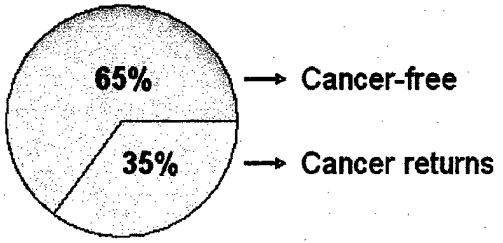
CMF

AC

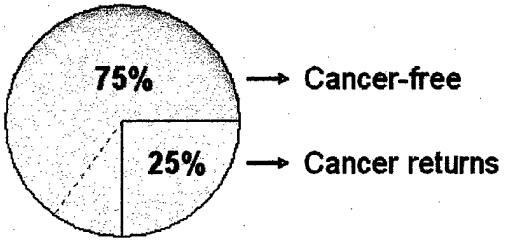
General Info

## INTRODUCTION
*(1 of 2)*

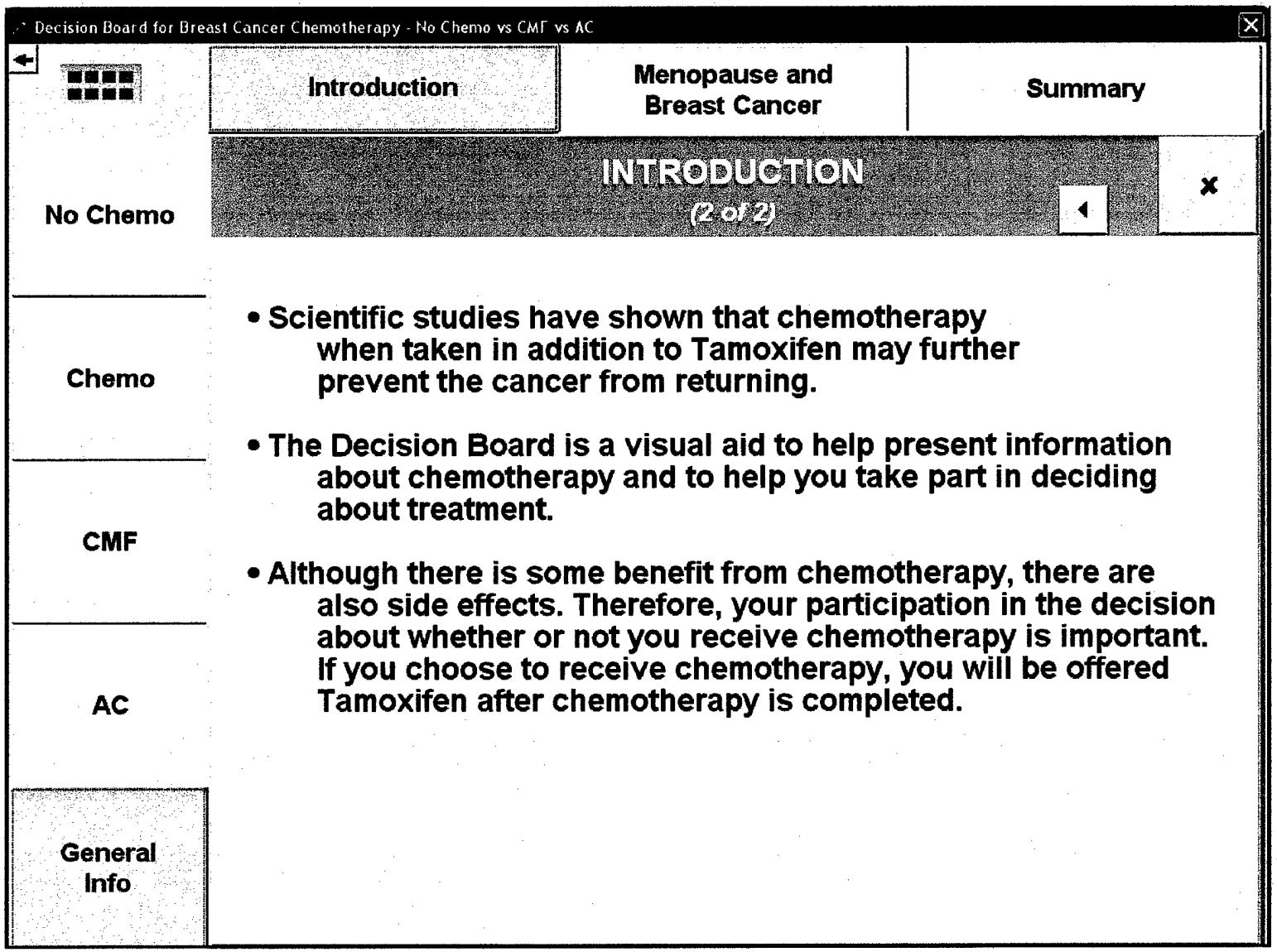
- Recently, you had surgery for cancer of the breast. The cancer was removed by either a lumpectomy or a mastectomy.
- Although the cancer was removed, it may still come back as a local recurrence (breast or chest wall) or a distant recurrence (e.g., liver, lung, bone).
- Unfortunately, cancer that comes back as a distant recurrence can be treated, but cannot be cured.
- Tamoxifen (pill for 5 years) will reduce your chances of cancer coming back.

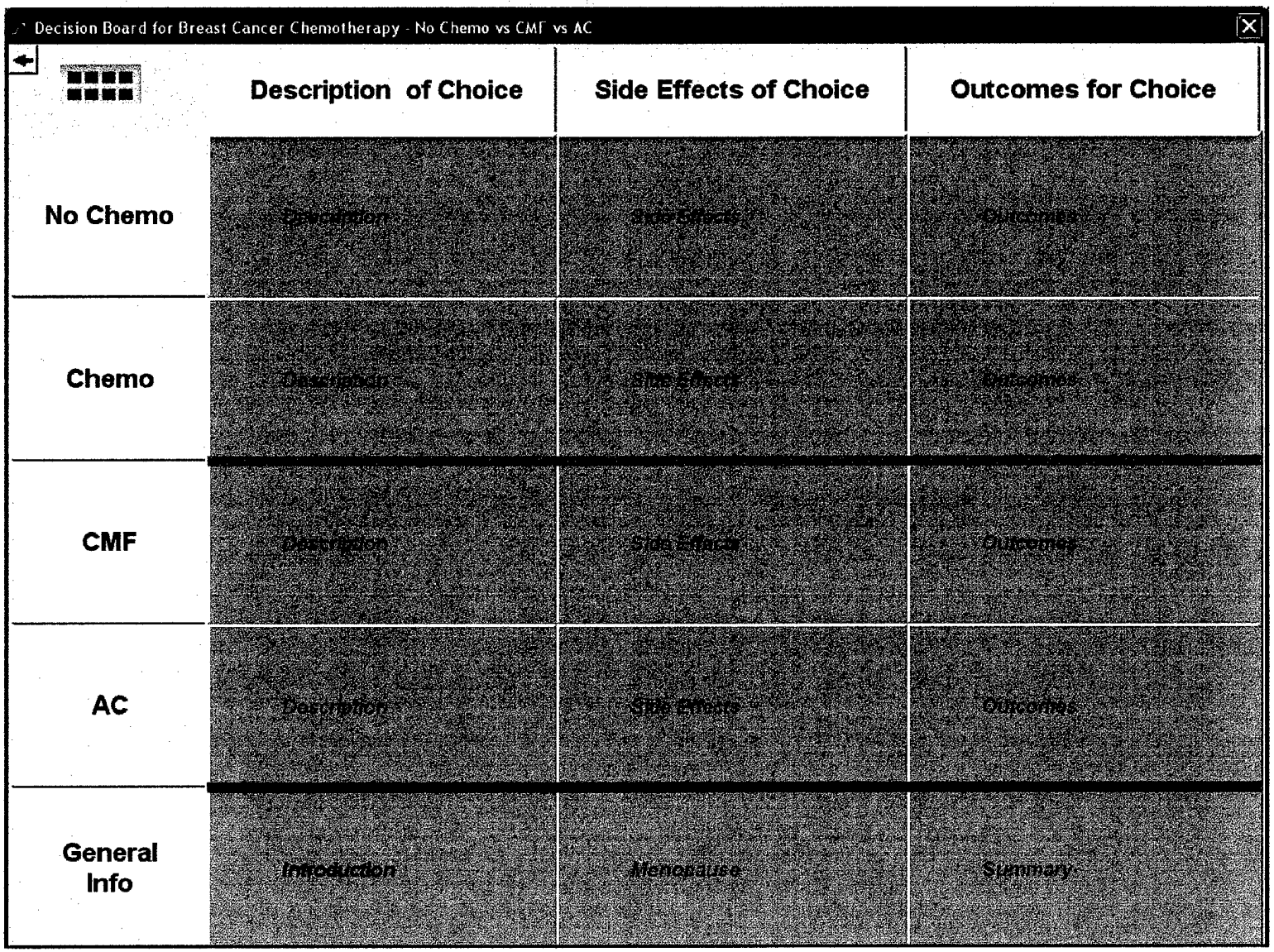


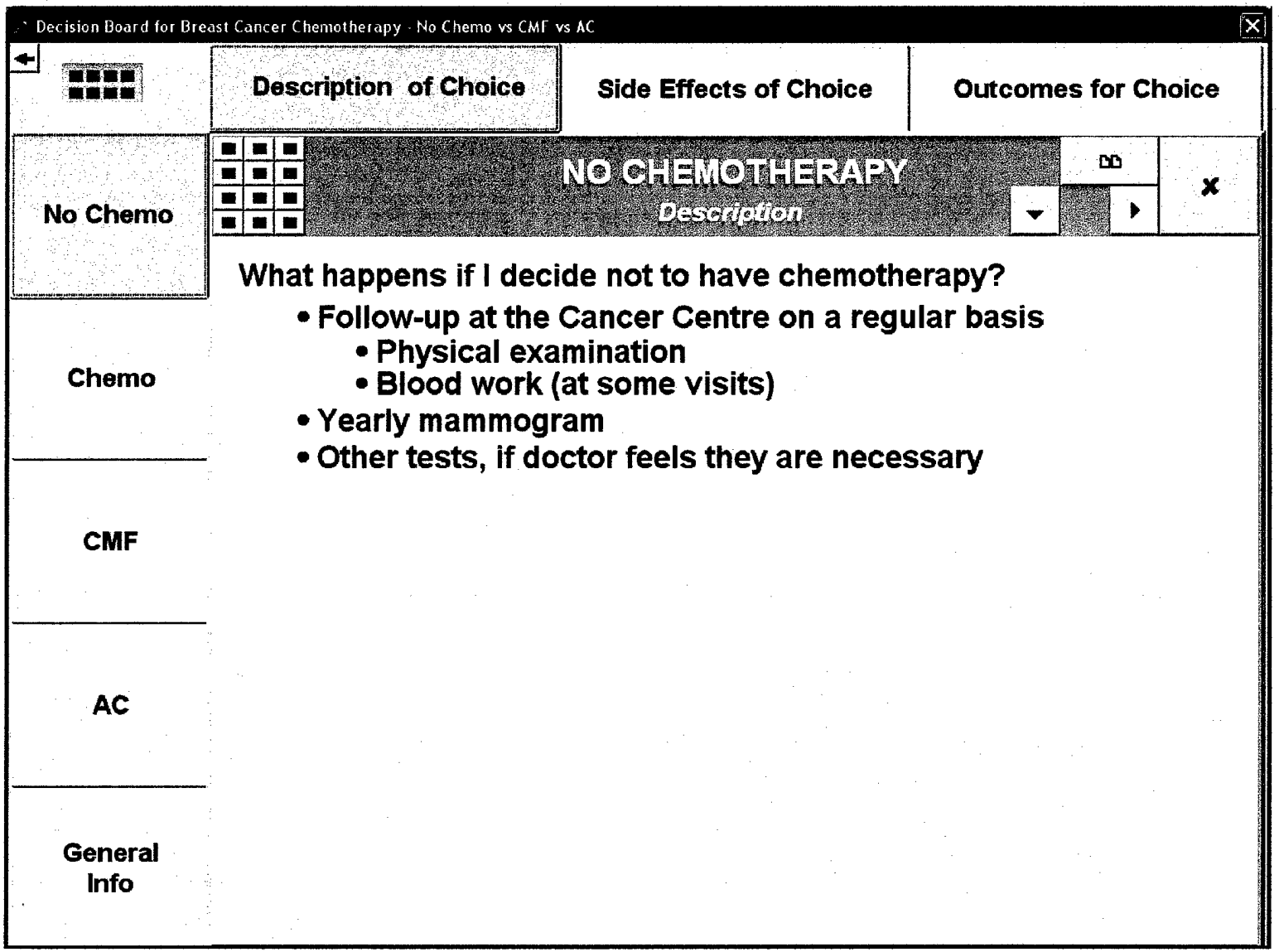

Without Tamoxifen or chemotherapy

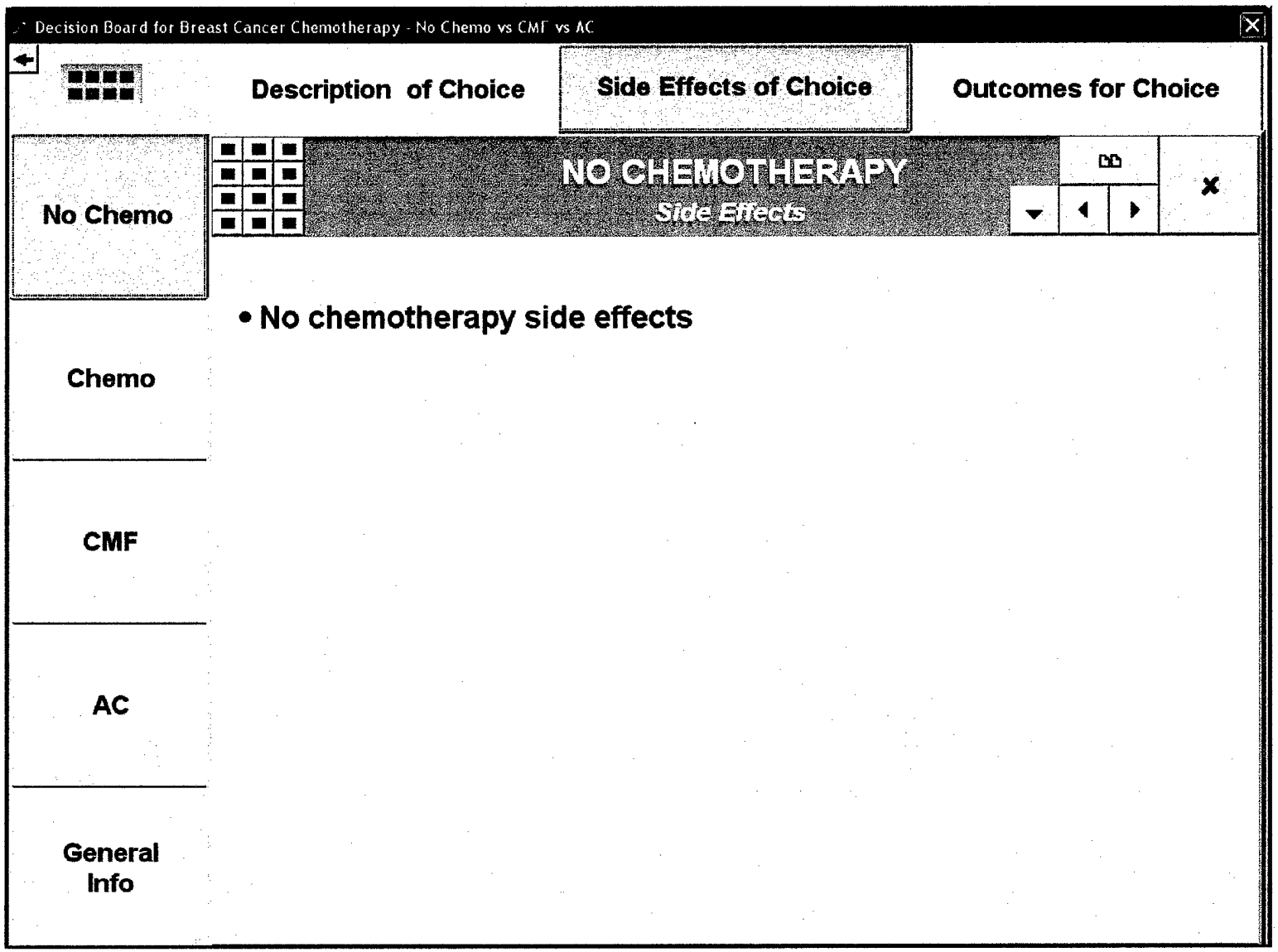


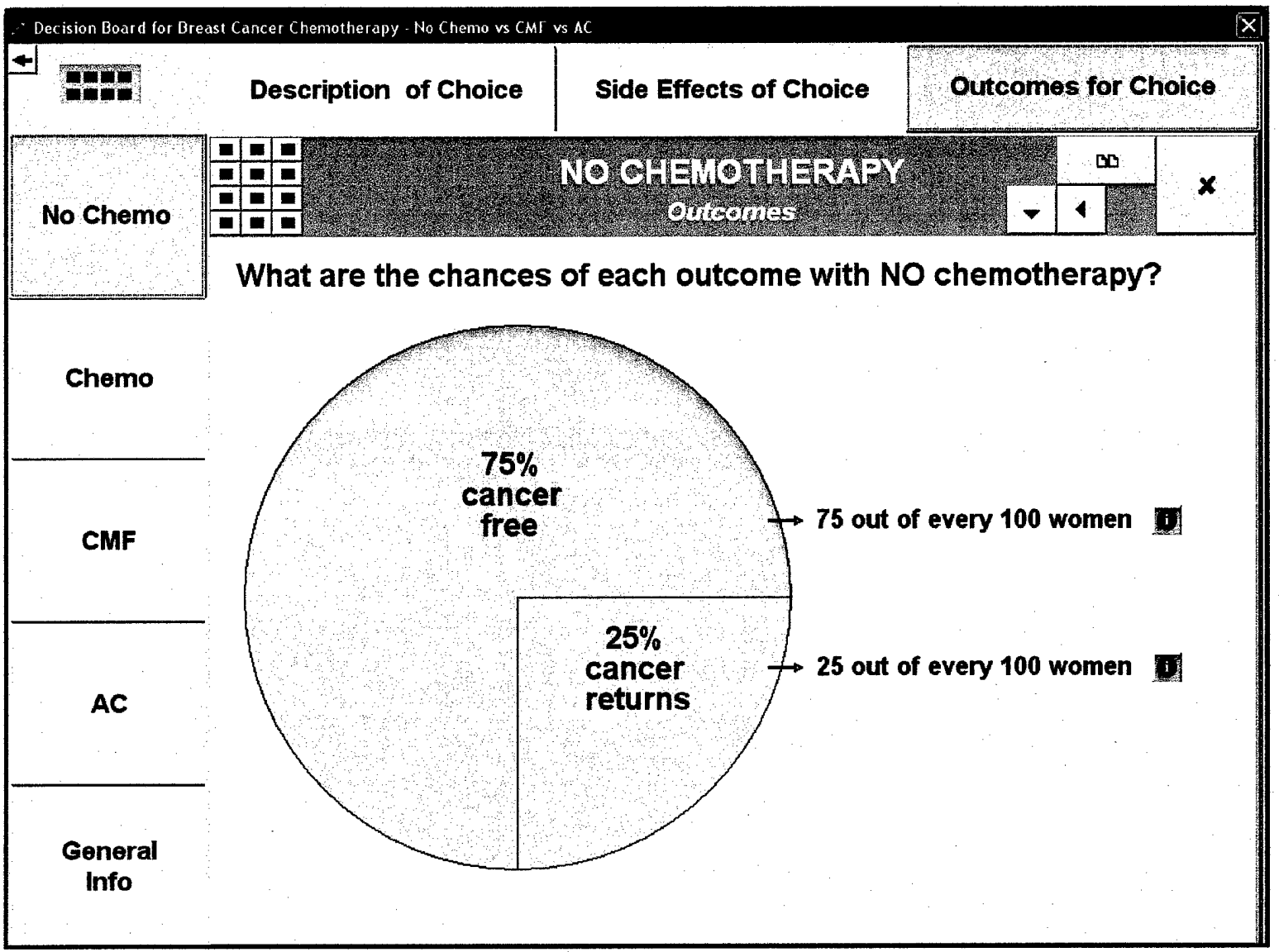

With Tamoxifen but no chemotherapy

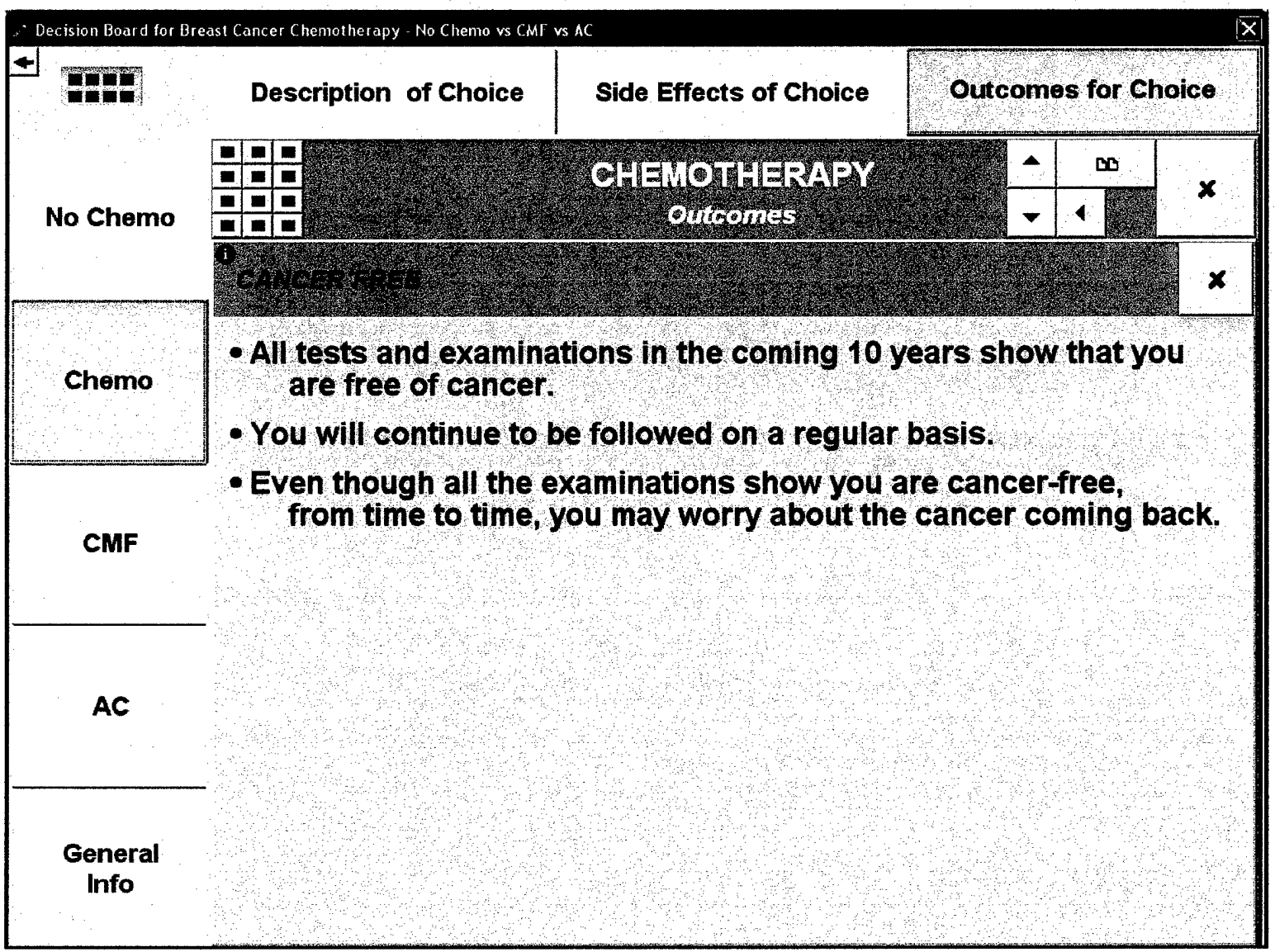

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Introduction
Menopause and Breast Cancer
Summary
INTRODUCTION
(2 of 2)
No Chemo
Chemo
CMF
AC
General Info
• Scientific studies have shown that chemotherapy when taken in addition to Tamoxifen may further prevent the cancer from returning.
• The Decision Board is a visual aid to help present information about chemotherapy and to help you take part in deciding about treatment.
• Although there is some benefit from chemotherapy, there are also side effects. Therefore, your participation in the decision about whether or not you receive chemotherapy is important. If you choose to receive chemotherapy, you will be offered Tamoxifen after chemotherapy is completed.

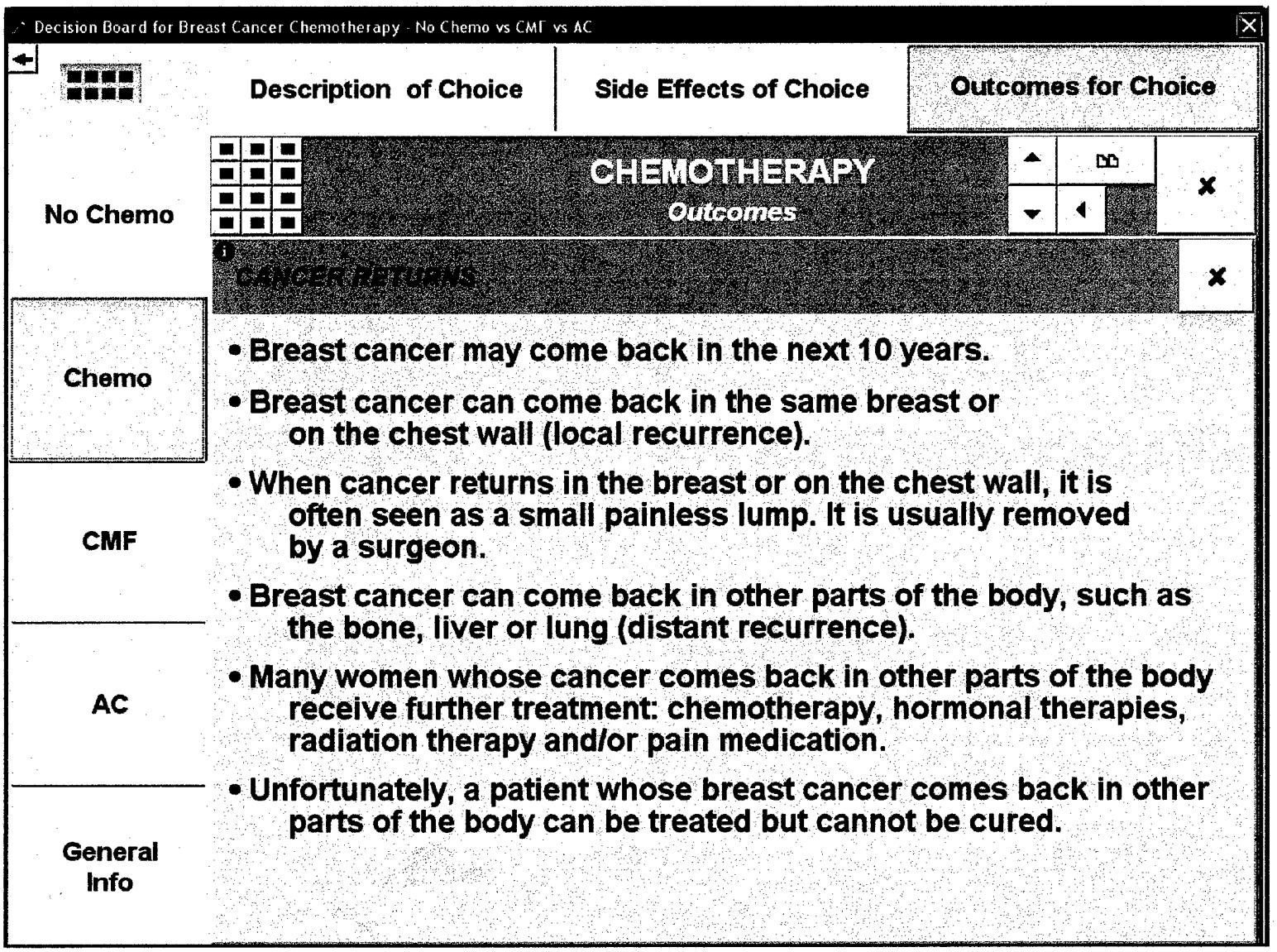

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
Description
Side Effects
Outcomes
Chemo
Description
Side Effects
Outcomes
CMF
Description
Side Effects
Outcomes
AC
Description
Side Effects
Outcomes
General Info
Introduction
Menopause
Summary


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
Chemo
CMF
AC
General Info
NO CHEMOTHERAPY
Description
What happens if I decide not to have chemotherapy?
• Follow-up at the Cancer Centre on a regular basis
• Physical examination
• Blood work (at some visits)
• Yearly mammogram
• Other tests, if doctor feels they are necessary


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
Chemo
CMF
AC
General Info
NO CHEMOTHERAPY
Side Effects
• No chemotherapy side effects

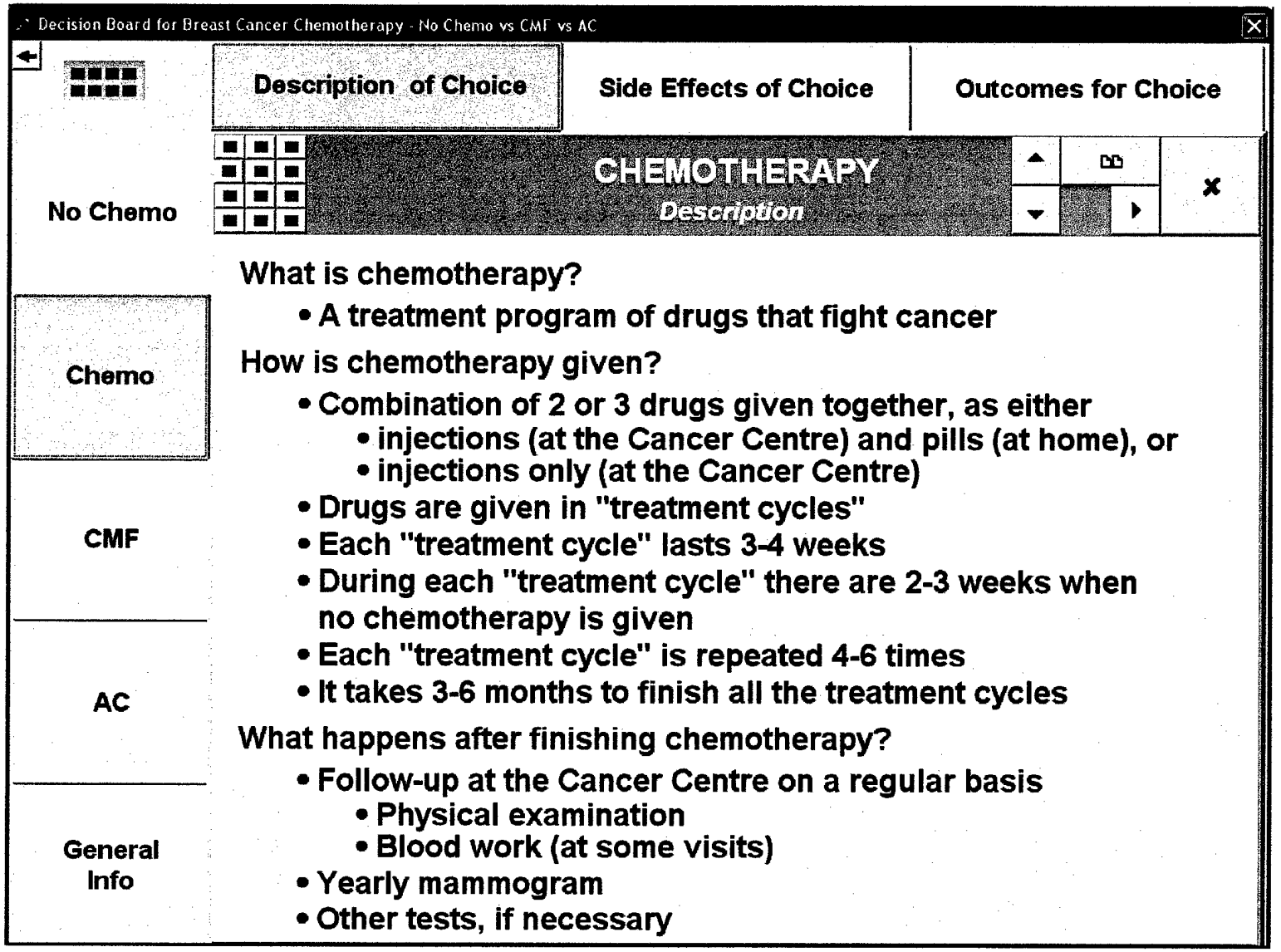

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
NO CHEMOTHERAPY
Outcomes
What are the chances of each outcome with NO chemotherapy?
Chemo
CMF
AC
General Info
75% cancer free
75 out of every 100 women
25% cancer returns
25 out of every 100 women

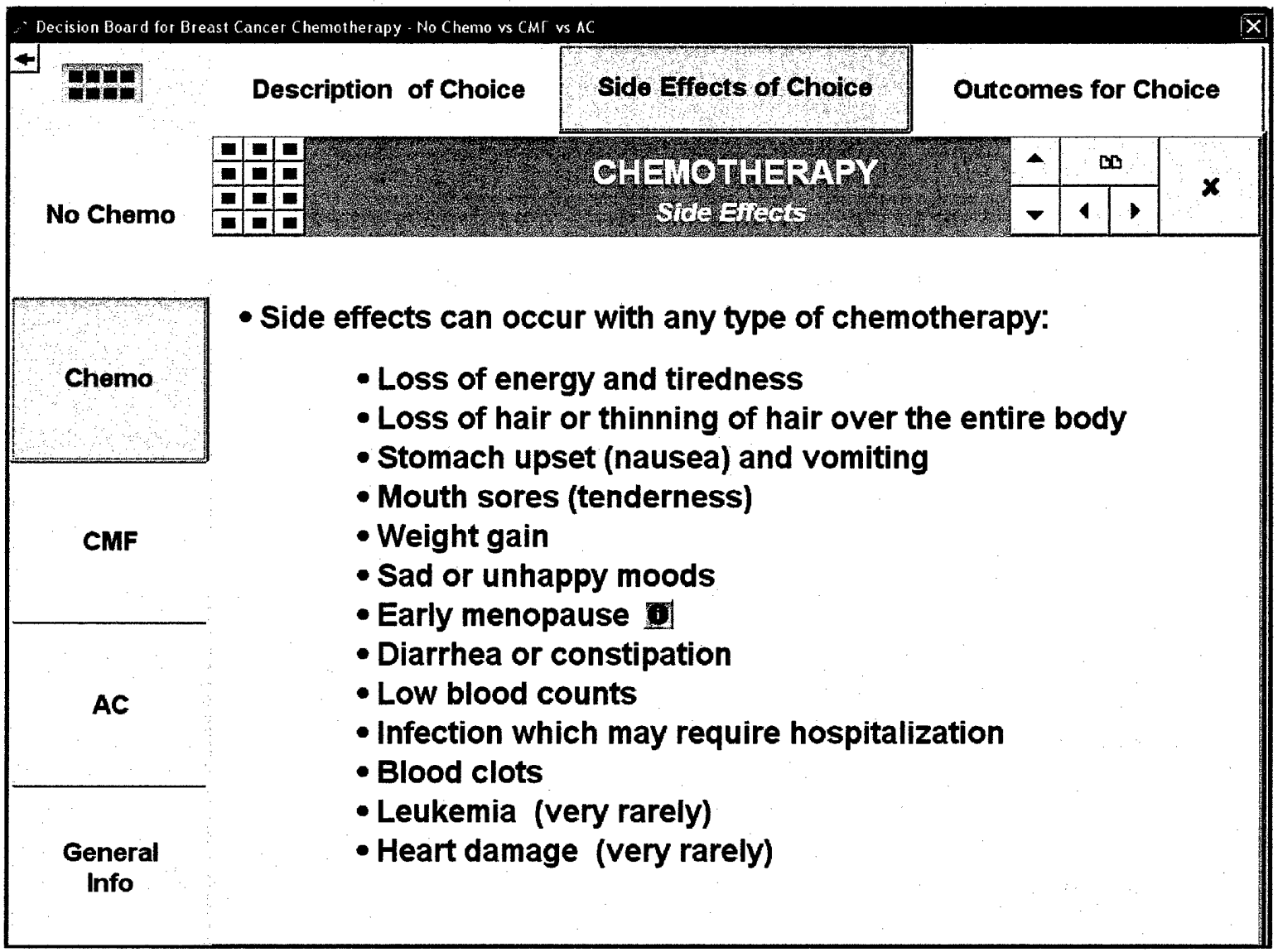

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
Chemo
CMF
AC
General Info
CHEMOTHERAPY
Outcomes
CANCER FREE
• All tests and examinations in the coming 10 years show that you are free of cancer.
• You will continue to be followed on a regular basis.
• Even though all the examinations show you are cancer-free, from time to time, you may worry about the cancer coming back.

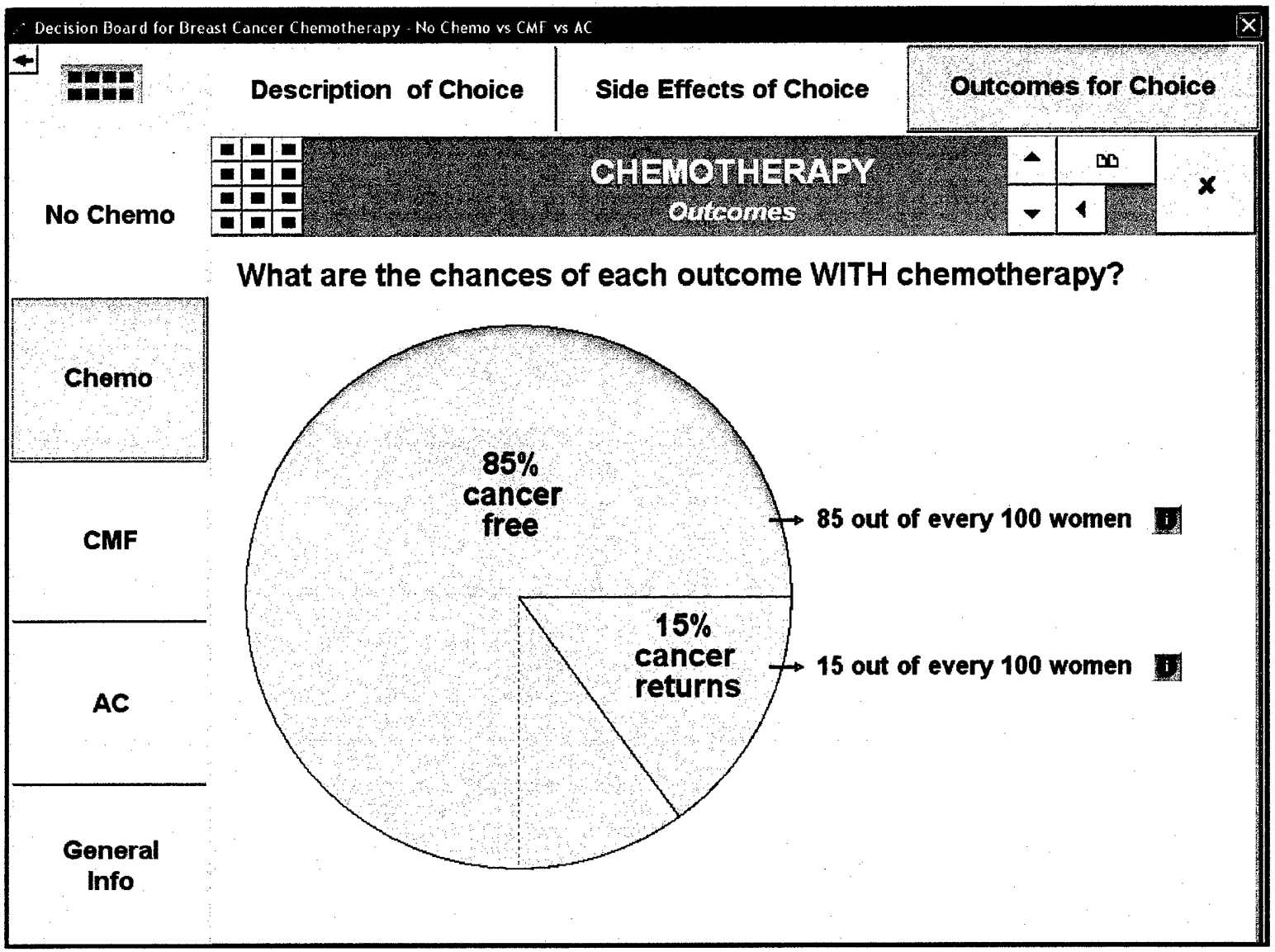

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
CHEMOTHERAPY
Outcomes
CANCER RETURNS
Chemo
• Breast cancer may come back in the next 10 years.
• Breast cancer can come back in the same breast or on the chest wall (local recurrence).
• When cancer returns in the breast or on the chest wall, it is often seen as a small painless lump. It is usually removed by a surgeon.
CMF
• Breast cancer can come back in other parts of the body, such as the bone, liver or lung (distant recurrence).
AC
• Many women whose cancer comes back in other parts of the body receive further treatment: chemotherapy, hormonal therapies, radiation therapy and/or pain medication.
• Unfortunately, a patient whose breast cancer comes back in other parts of the body can be treated but cannot be cured.
General Info

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

| | Description of Choice | Side Effects of Choice | Outcomes for Choice |
|---|---|---|---|
| No Chemo | Regular follow-up at the Cancer Centre | No chemotherapy side effects | 75% cancer-free 25% cancer returns |
| Chemo | Description | Side Effects | Outcomes |
| CMF | Description | Side Effects | Outcomes |
| AC | Description | Side Effects | Outcomes |
| General Info | Introduction | Menopause | Summary |


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
CHEMOTHERAPY
Description
Chemo
CMF
AC
General Info
What is chemotherapy?
• A treatment program of drugs that fight cancer
How is chemotherapy given?
• Combination of 2 or 3 drugs given together, as either
• injections (at the Cancer Centre) and pills (at home), or
• injections only (at the Cancer Centre)
• Drugs are given in "treatment cycles"
• Each "treatment cycle" lasts 3-4 weeks
• During each "treatment cycle" there are 2-3 weeks when no chemotherapy is given
• Each "treatment cycle" is repeated 4-6 times
• It takes 3-6 months to finish all the treatment cycles
What happens after finishing chemotherapy?
• Follow-up at the Cancer Centre on a regular basis
• Physical examination
• Blood work (at some visits)
• Yearly mammogram
• Other tests, if necessary


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
CHEMOTHERAPY
Side Effects
Chemo
CMF
AC
General Info
• Side effects can occur with any type of chemotherapy:
• Loss of energy and tiredness
• Loss of hair or thinning of hair over the entire body
• Stomach upset (nausea) and vomiting
• Mouth sores (tenderness)
• Weight gain
• Sad or unhappy moods
• Early menopause
• Diarrhea or constipation
• Low blood counts
• Infection which may require hospitalization
• Blood clots
• Leukemia (very rarely)
• Heart damage (very rarely)


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
CHEMOTHERAPY
Outcomes
What are the chances of each outcome WITH chemotherapy?
Chemo
CMF
AC
General Info
85% cancer free
85 out of every 100 women
15% cancer returns
15 out of every 100 women

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

| | Description of Choice | Side Effects of Choice | Outcomes for Choice |
|---|---|---|---|
| No Chemo | | | |
| Chemo | | | |
| CMF | Description | Side Effects | Outcomes |
| AC | Description | Side Effects | Outcomes |
| General Info | Introduction | Menopause | Summary |

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

**Description of Choice** | **Side Effects of Choice** | **Outcomes for Choice**

**No Chemo**

**Chemo**

**CMF**

**AC**

**General Info**

## CMF Chemotherapy

*Description*

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---|---|---|---|---|---|---|---|
| Week 1 | | | | | | | |
| Week 2 | | | | | | | |
| Week 3 | No Chemotherapy | | | | | | |
| Week 4 | No Chemotherapy | | | | | | |

x 6 =

6 months

- "Treatment cycle" lasts **4 weeks**
- 3 chemotherapy drugs:
  - Cyclophosphamide
    - pills taken by mouth
    - every day for first 2 weeks of each treatment cycle
  - Methotrexate and Fluorouracil
    - given intravenously
    - two times: Day 1 of first week and Day 1 of second week in each treatment cycle
    - takes about 20 minutes to receive intravenous drugs
- Treatment cycle is repeated 6 times for a total of **6 months**

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

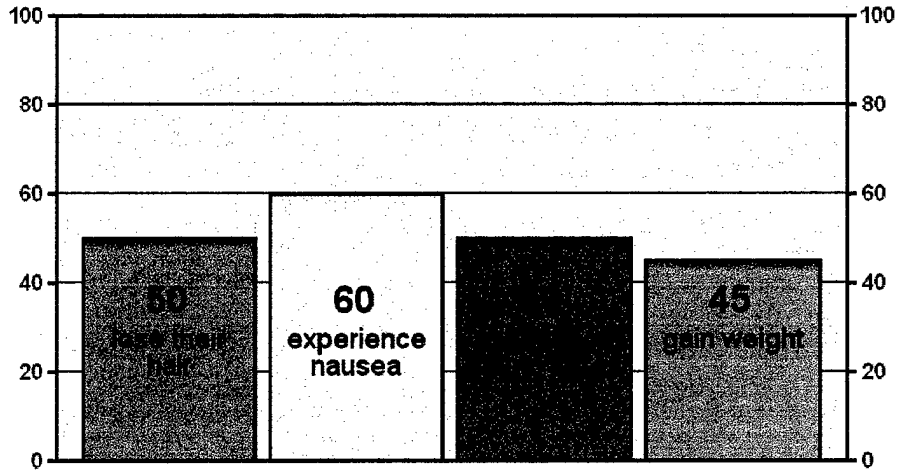
CMF

AC

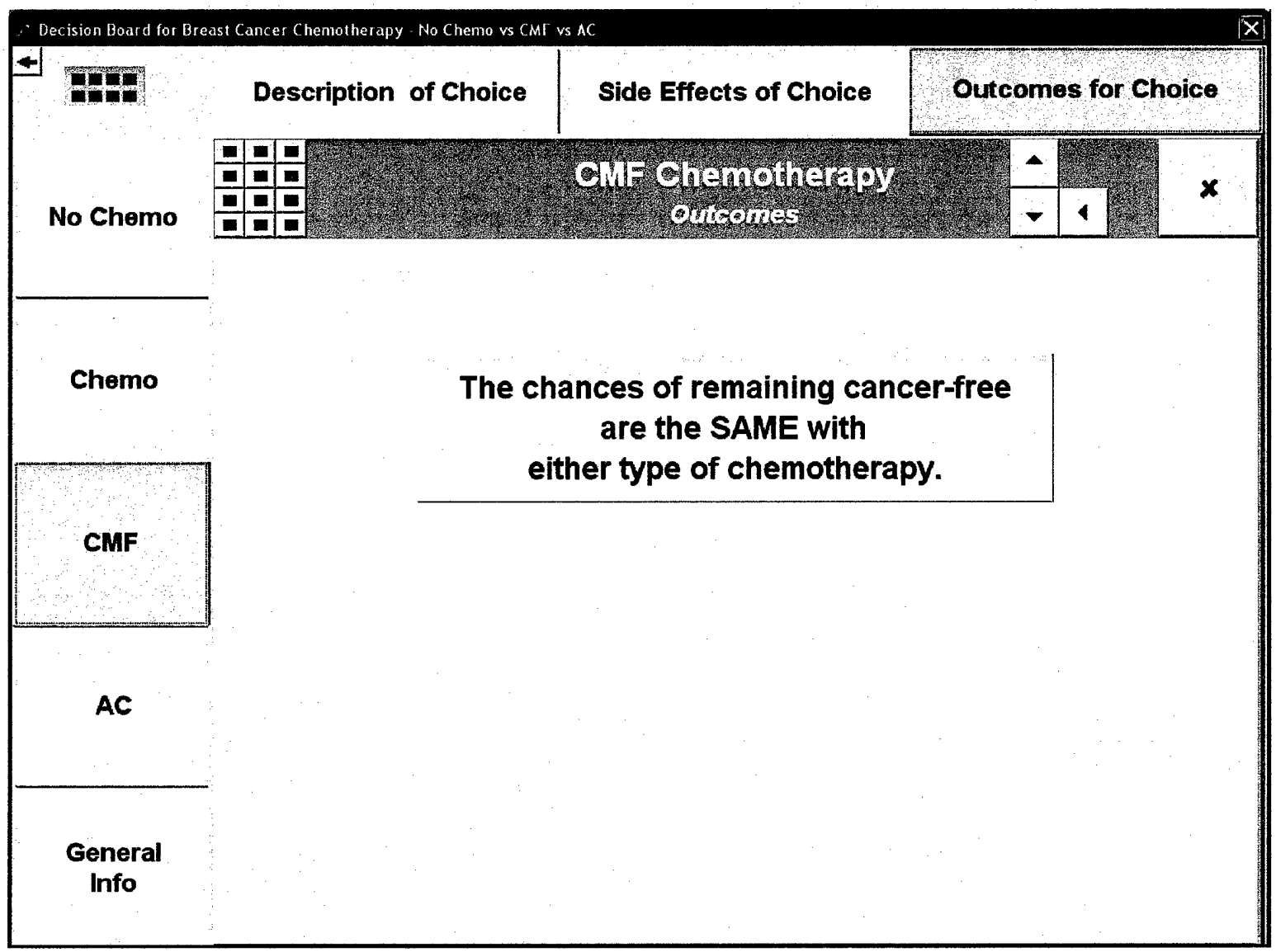
General Info

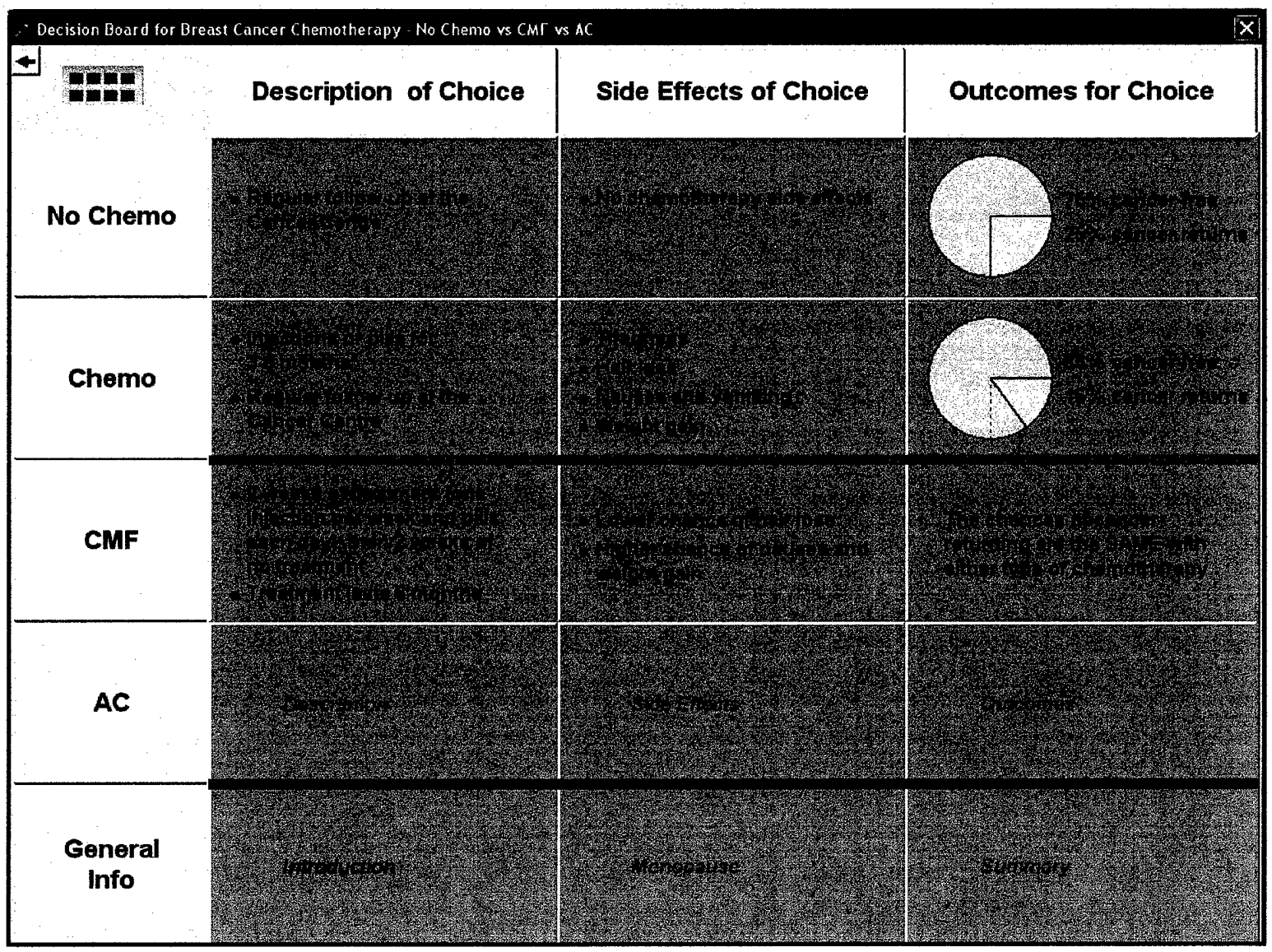
## CMF Chemotherapy
*Side Effects*

- For every 100 women taking CMF chemotherapy:




- With CMF, very few women will experience serious side effects such as infection (10 in 1000), leukemia (2 in 1000) or heart damage (virtually none).


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
CMF Chemotherapy
Outcomes
Chemo
The chances of remaining cancer-free
are the SAME with
either type of chemotherapy.
CMF
AC
General
Info


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
Chemo
CMF
AC
General Info
Introduction
Menopause
Summary

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

CMF

AC

General Info

## AC Chemotherapy

*Description*

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---|---|---|---|---|---|---|---|
| Week 1 | | No Chemotherapy | | | | | |
| Week 2 | | No Chemotherapy | | | | | |
| Week 3 | | No Chemotherapy | | | | | |

x 4 = 3 months

- "Treatment cycle" lasts **3 weeks**
- 2 chemotherapy drugs:
  - Adriamycin and Cyclophosphamide
    - given intravenously
    - one time only: first day of each treatment cycle
    - takes about 60 minutes to receive intravenous drugs
- Treatment cycle is repeated 4 times for a total of **3 months**

Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC

Description of Choice | Side Effects of Choice | Outcomes for Choice

No Chemo

Chemo

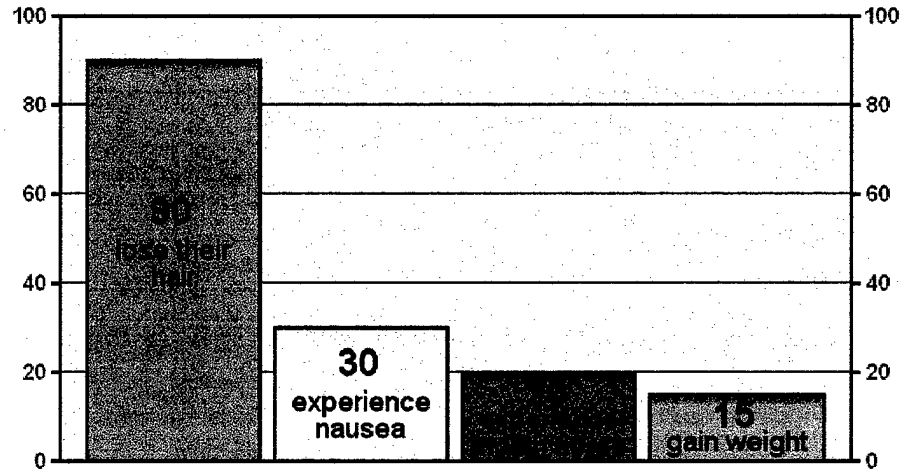
CMF

AC

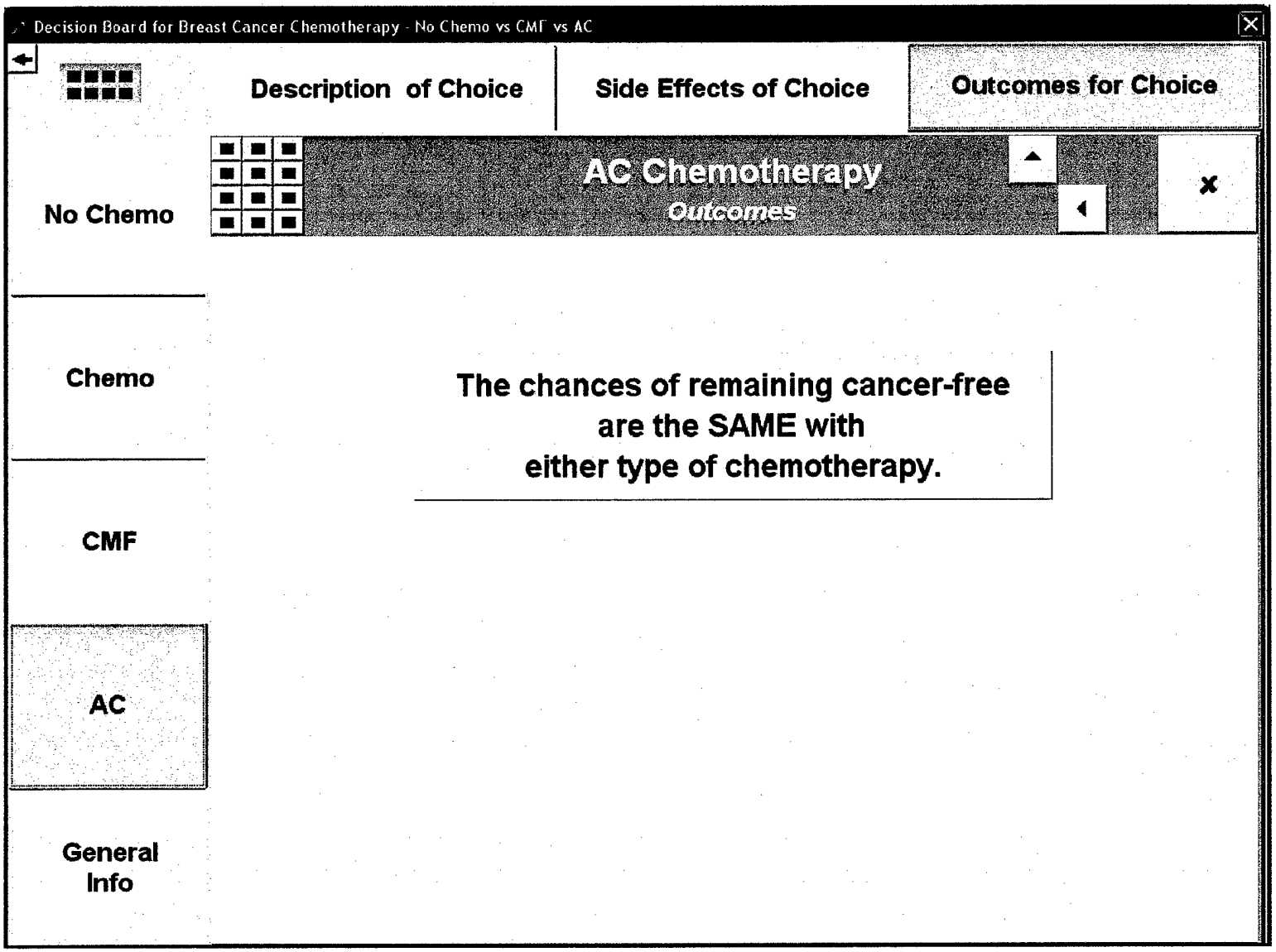
General Info

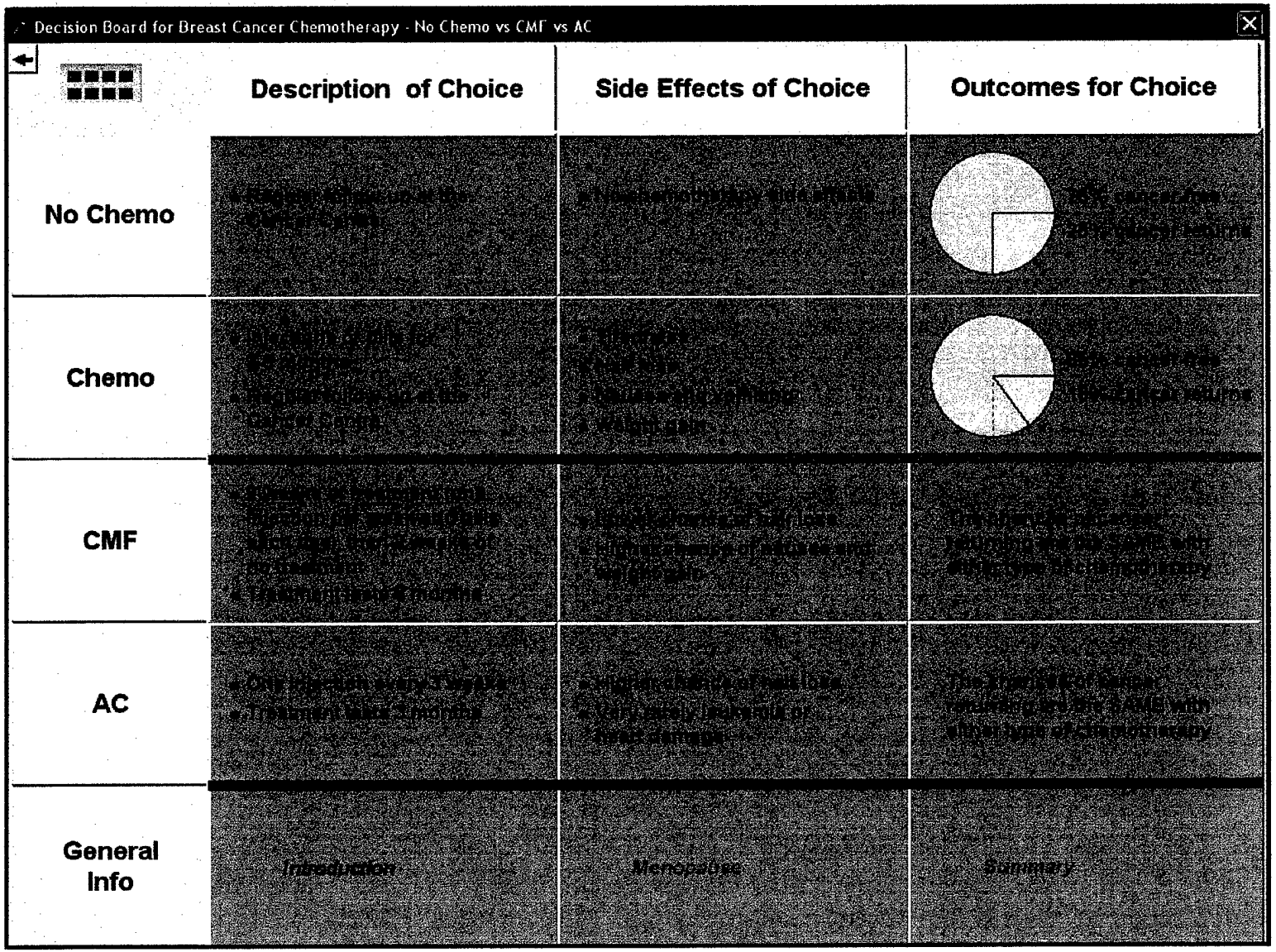
## AC Chemotherapy
*Side Effects*

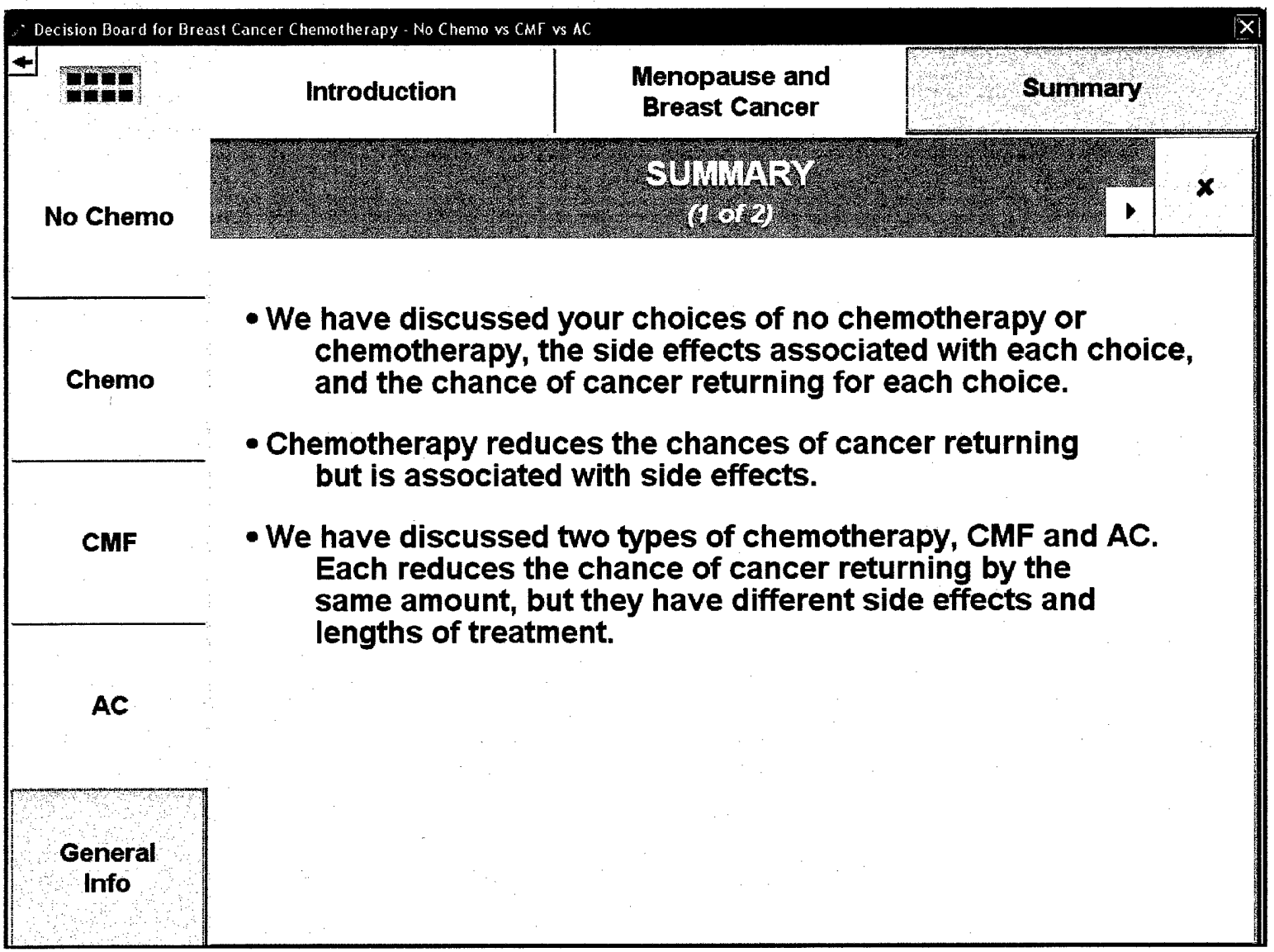
- For every 100 women taking AC chemotherapy:

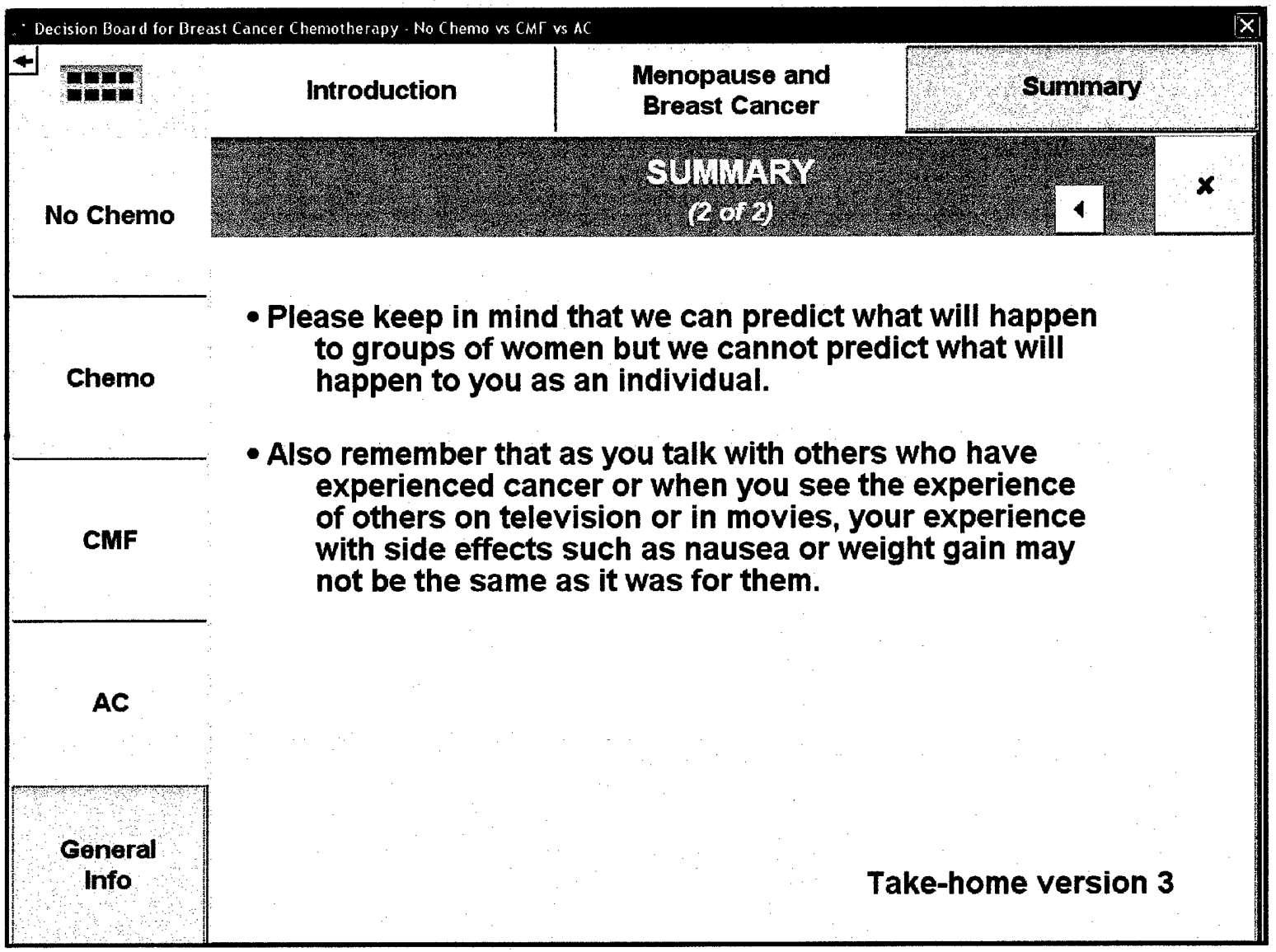



- With AC, very few women will experience serious side effects such as infection (20 in 1000), leukemia (4 in 1000) or heart damage (2 in 1000).


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
AC Chemotherapy
Outcomes
Chemo
The chances of remaining cancer-free
are the SAME with
either type of chemotherapy.
CMF
AC
General
Info


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Description of Choice
Side Effects of Choice
Outcomes for Choice
No Chemo
Chemo
CMF
AC
General Info
Introduction
Menopause
Summary


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Introduction
Menopause and Breast Cancer
Summary
No Chemo
Chemo
CMF
AC
General Info
SUMMARY
(1 of 2)
• We have discussed your choices of no chemotherapy or chemotherapy, the side effects associated with each choice, and the chance of cancer returning for each choice.
• Chemotherapy reduces the chances of cancer returning but is associated with side effects.
• We have discussed two types of chemotherapy, CMF and AC. Each reduces the chance of cancer returning by the same amount, but they have different side effects and lengths of treatment.


Decision Board for Breast Cancer Chemotherapy - No Chemo vs CMF vs AC
Introduction
Menopause and Breast Cancer
Summary
No Chemo
Chemo
CMF
AC
General Info
SUMMARY
(2 of 2)
• Please keep in mind that we can predict what will happen to groups of women but we cannot predict what will happen to you as an individual.
• Also remember that as you talk with others who have experienced cancer or when you see the experience of others on television or in movies, your experience with side effects such as nausea or weight gain may not be the same as it was for them.
Take-home version 3

# Appendix 4

## DECIDE-S Standard Take-Home Example

*(Axillary Node Dissection Version)*

# DECISION BOARD

## INTRODUCTION

- Breast cancer can be treated in a variety of ways including surgery, radiation, chemotherapy and hormonal therapy.
- The first step in the treatment of breast cancer is to remove the cancer by surgery.
- There are two types of surgery:
    - Mastectomy, which results in the loss of the breast, and usually no radiation is required.
    - Lumpectomy, which involves removal of the part of the breast that contains cancer, radiation to the breast is then part of the treatment.
- Medical studies have shown that the chance of surviving cancer is the same with either type of surgery.
- Both of these treatments also include an axillary node dissection (removal of nodes or glands under your arm).
- If cancer spreads to these nodes, there is a higher chance that the cancer may spread to other parts of the body. This is important information for you and your doctor to know to help decide if other treatments, such as hormonal therapy or chemotherapy are necessary.
- The Decision Board is a visual aid to help present information about these two surgical treatments and to help you take part in deciding about treatment.
- It is important to remember that there is no right or wrong decision.

Version 1

Supportive Cancer Care Research Unit
Hamilton Regional Cancer Centre
699 Concession St., Level 3-60
Hamilton, ON L8V 5C2

# DECISIO

## TREATMENT CHOICE

### MASTECTOMY
*(Surgical Removal of the Breast)*

- The entire breast will be removed.
- Some lymph nodes under your arm will be removed.
- A drain is inserted near the scar under the arm for 5 to 10 days to remove excess fluid.
- After surgery, you may be referred to the Cancer Centre for consideration of other treatments (hormonal therapy or chemotherapy).
- Radiation is not usually necessary.

### LUMPECTOMY
*(Surgical Removal of the Cancerous Lump)*

- Only the cancerous lump and some surrounding tissue will be removed.
- Some lymph nodes under your arm will be removed.
- A drain is inserted near the scar under the arm for 5 to 10 days to remove excess fluid.
- In about 1 out of 10 women, all the cancer in the breast may not be removed and further surgery may be necessary.
- After the breast has healed, you will be referred to the Cancer Centre for radiation therapy.

**PLUS**

### RADIATION
*(X-ray Treatment)*

- You will need to meet with a radiation oncologist at the Cancer Centre to plan radiation treatments.
- The time between your surgery and the beginning of your radiation treatments may be 6 to 12 weeks.
- Your treatments will be daily for 3 to 5 weeks, excluding weekends and holidays.
- Each visit lasts about 30 to 45 minutes.
- Other treatments (hormonal therapy and chemotherapy) may be considered.
- If you are treated with chemotherapy, your radiation will begin when the chemotherapy is finished.

## SIDE EFFECTS

### MASTECTOMY

*OFTEN*
- Numbness and discomfort under the arm where the nerves were cut.
- Pain, discomfort or numbness of the chest.

*SOMETIMES*
- Stiffness of the shoulder.

*RARELY*
- Infection.
- Swelling of the arm.

### LUMPECTOMY

*OFTEN*
- Numbness and discomfort under the arm where the nerves were cut.
- Pain or discomfort of the breast.

*SOMETIMES*
- Stiffness of the shoulder.

*RARELY*
- Infection.
- Swelling of the arm.

**PLUS**

RADIATION

*OFTEN*
- Redness of the skin like a sunburn.

*SOMETIMES*
- Increased tiredness.
- Temporary swelling of the breast.
- Slight increase in firmness of the breast.

*RARELY*
- Blood vessels may become visible on small areas of the skin.
- Other side effects occur very rarely (e.g., pneumonitis - a temporary cough and shortness of breath).

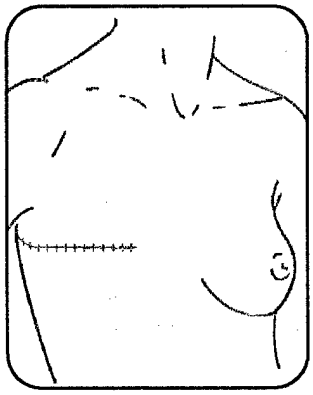
# N BOARD

## RESULTS OF TREATMENT CHOICE

**For The Breast** **For Survival**

### MASTECTOMY

- You are left with a healed scar across your chest.
- Some women may be upset by the loss of their breast.
- A breast prosthesis or breast form can be fitted.
- The breast can be reconstructed using plastic surgery.
- Cancer may come back on the chest. About 5 to 10 out of 100 women will experience this in the next 10 years.
- Cancer that comes back on the chest is usually treated with surgery, radiation, or both.

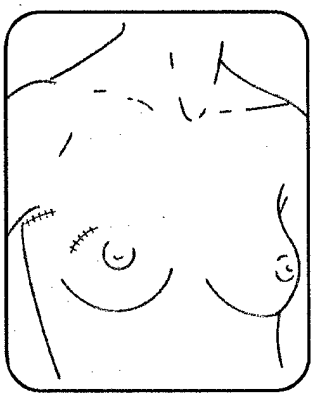


### MASTECTOMY

*Your chance of surviving cancer is the SAME as with Lumpectomy plus Radiation.*

### LUMPECTOMY PLUS RADIATION

- You are left with two healed scars: one on the breast and one under the arm.
- There may be some indentation where the lump was removed or thickening of the breast tissue.
- Some women may be upset by the appearance of the breast, but most (8 out of 10 women) are comfortable with the way their breast looks.
- Cancer may come back in the same breast. About 5 to 10 out of 100 women will experience this in the next 10 years.
- Cancer that comes back in the same breast is usually removed by further surgery (lumpectomy or mastectomy). Radiation cannot be given again to the same breast.



### LUMPECTOMY PLUS RADIATION

*Your chance of surviving cancer is the SAME as with Mastectomy.*

# SUMMARY

- We have discussed your choices for surgery, the side effects and the results of each choice.
- Remember, the chances of survival are the same for both choices.
- In deciding between the two options, think about the issues that will affect your day-to-day life.
- You may want to consider some of the following issues:
    - How will the results of your treatment choice affect your daily activities, for example, the way you dress or the style of clothing you like to wear?
    - Will the treatment you choose be inconvenient for you? Consider the length of the treatment and the need to travel to the Cancer Centre?
    - How will the results of your treatment choice affect the way you feel about yourself, your body and your sexuality?
    - Will your concern about cancer returning be lessened with one type of surgery over another?
- Keep in mind that every woman is different and you should choose the option that is best for you.

# CHEMOTHERAPY AND HORMONAL THERAPY

- Whether you are a candidate for other therapies depends on the size of your tumour and whether the lymph nodes are involved. These therapies include chemotherapy and/or hormonal therapy.

- Chemotherapy is a treatment program of drugs designed to kill cancer cells. Chemotherapy is usually given by injection only or as a combination of injection and pills. The treatments last from three to six months.

- Hormonal therapy is offered to women if the tests done on the tumour show that there are receptors for female hormones on the cancer cells. Hormonal therapy is given in pill form. One pill is taken each day for five years.

# MASTECTOMY AND RADIATION

- Radiation is sometimes given after mastectomy for women at high risk of cancer coming back on the chest wall. For example, women with large cancers (> 5 cm) or women with many lymph nodes involved may be offered radiation.

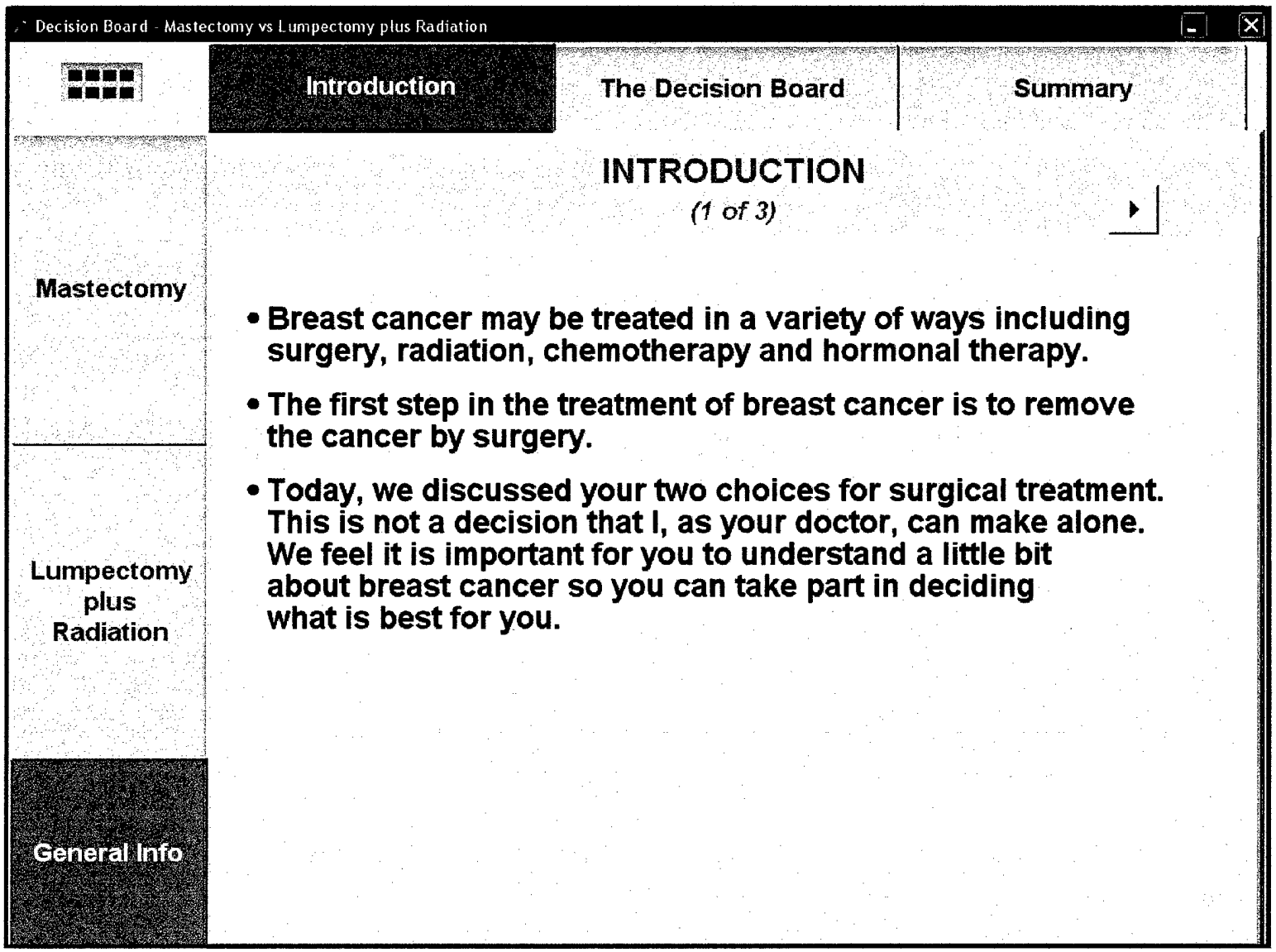
# BREAST RECONSTRUCTION

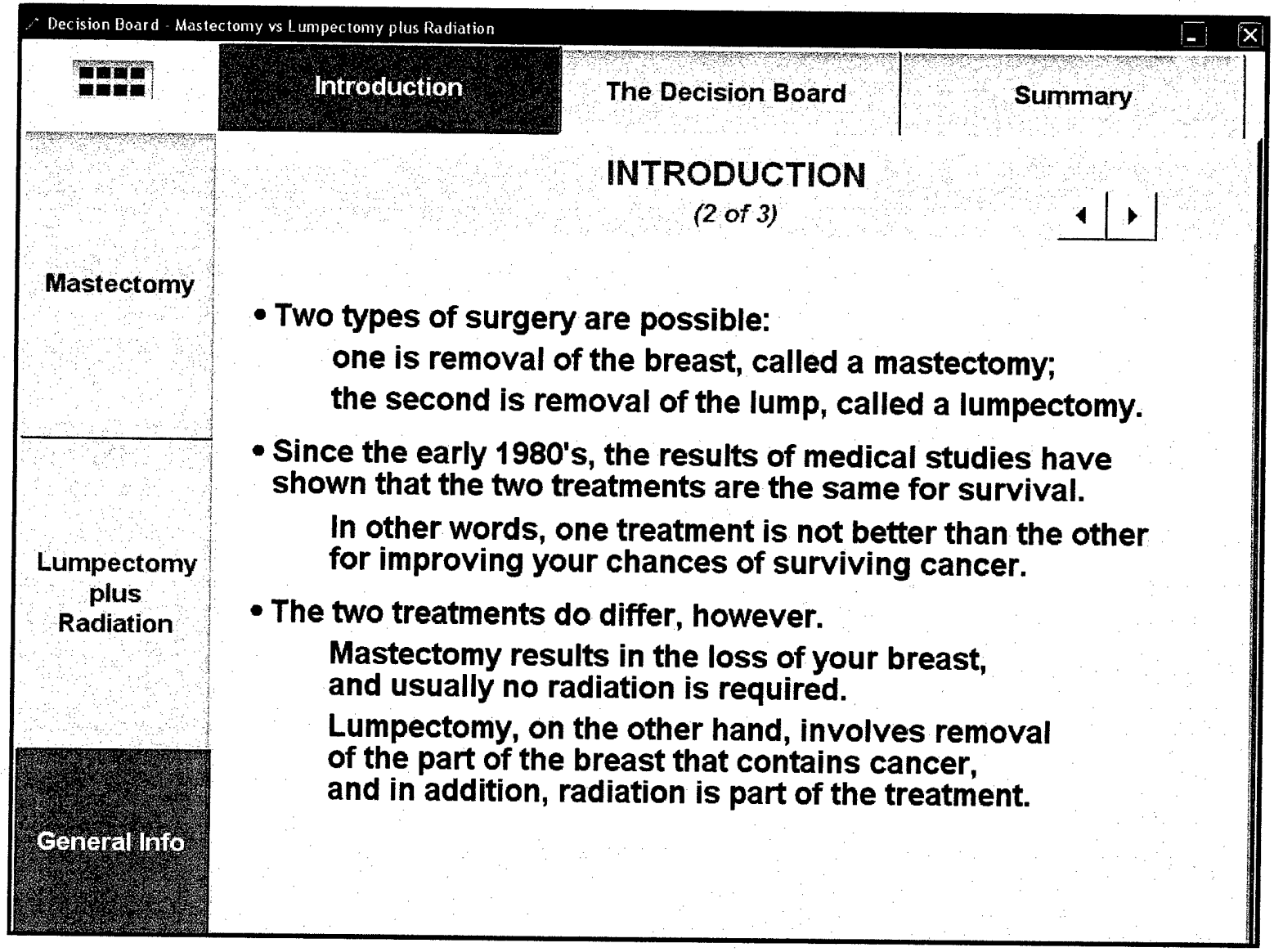
- Following mastectomy, the breast can be reconstructed using plastic surgery.
- You will need to meet with the plastic surgeon to discuss the procedure in more detail.
- Breast reconstruction is performed in one of two ways:
    - Using a saline (salt-water) filled implant inserted under the skin, or
    - With more extensive surgery using your own tissue (often taken from your abdomen)
- Reconstruction of the breast can be performed simultaneously with mastectomy or the procedure can be done at a later time.
- With current surgical techniques, the reconstructed breast often looks similar to your normal breast.

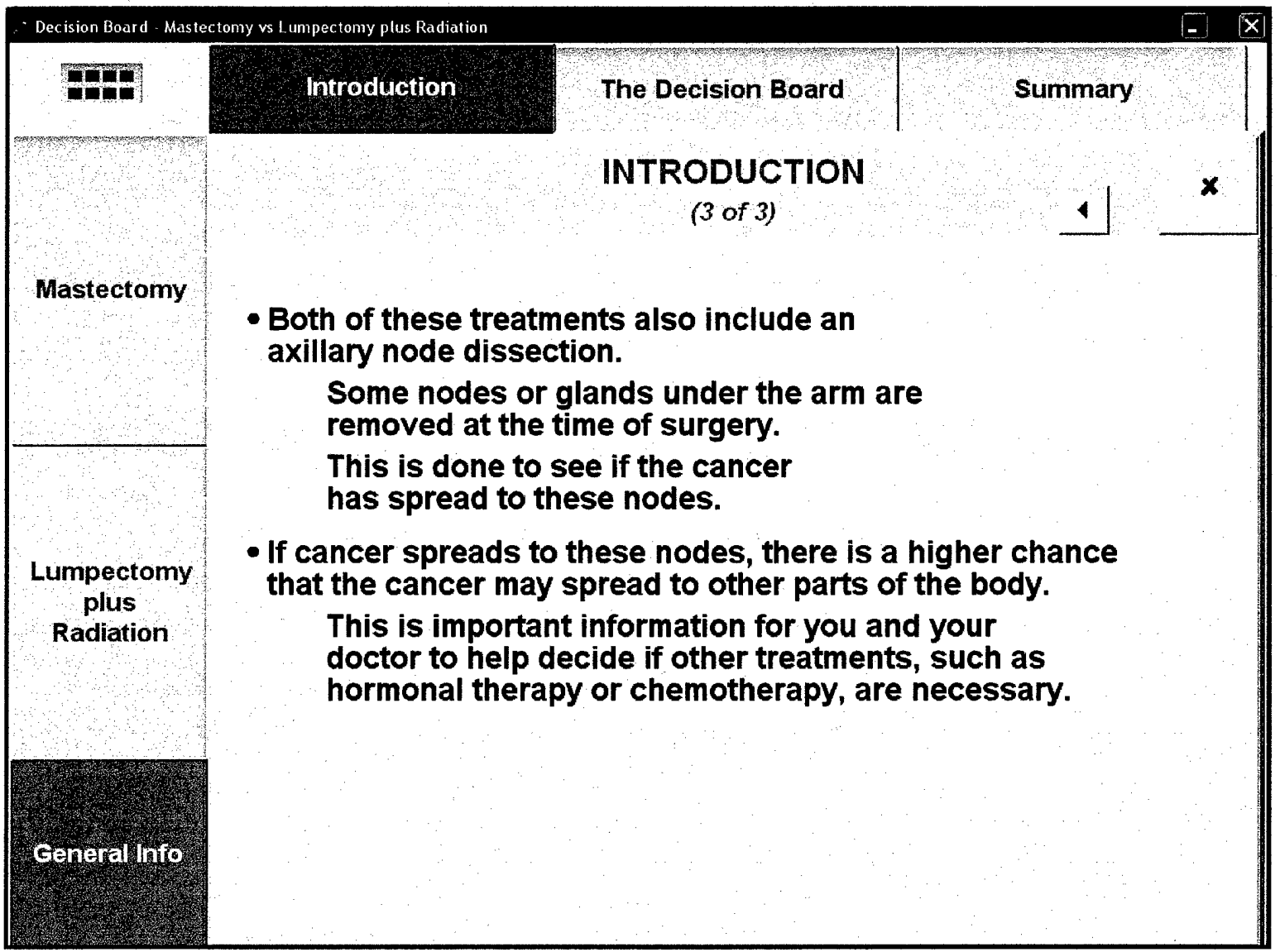
# Appendix 5

## DECIDE-C Computer Take-Home Example

*(Axillary Node Dissection Version)*

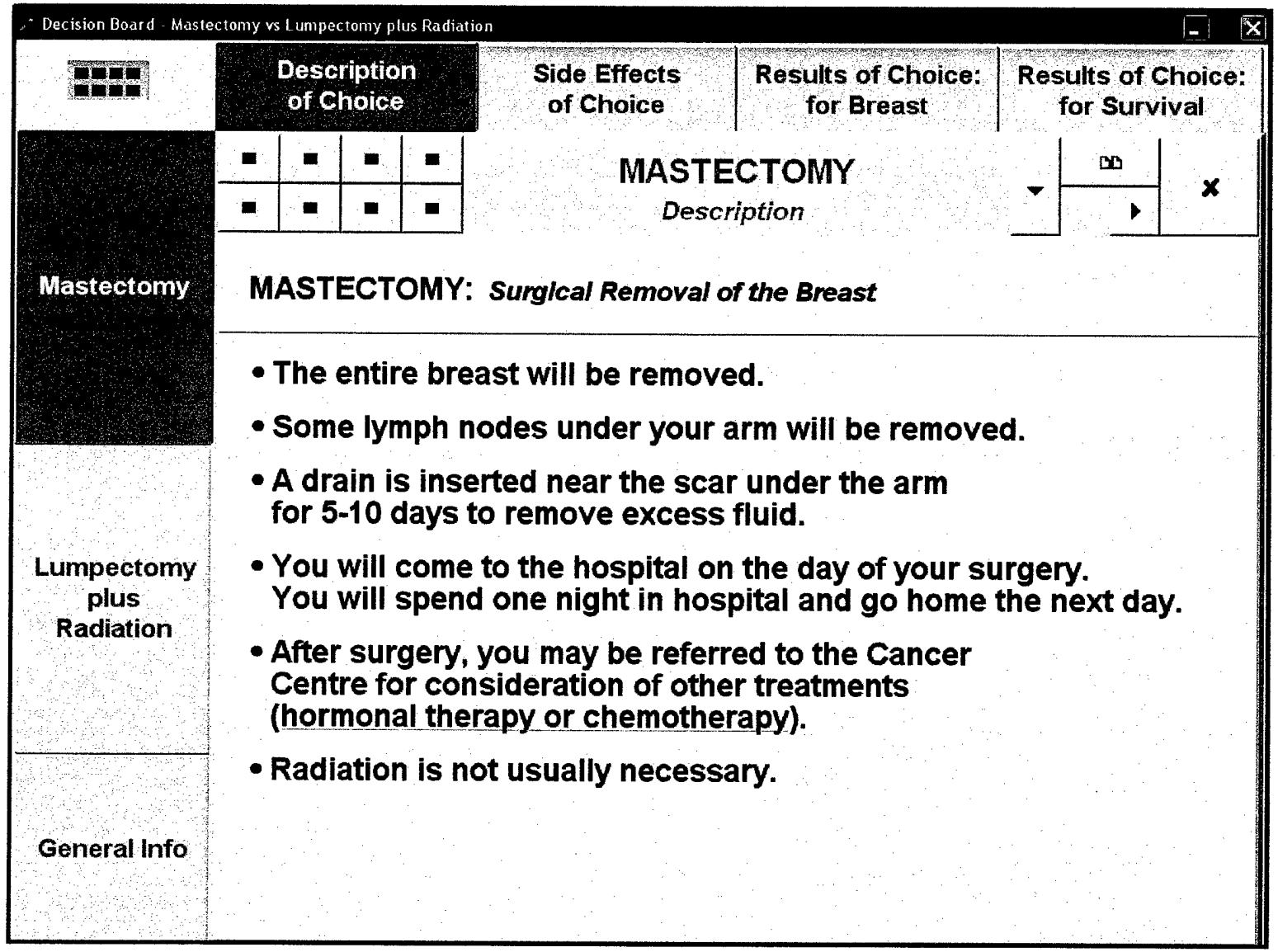

Decision Board - Mastectomy vs Lumpectomy plus Radiation
Introduction
The Decision Board
Summary
Mastectomy
Lumpectomy plus Radiation
General Info
INTRODUCTION
(1 of 3)
• Breast cancer may be treated in a variety of ways including surgery, radiation, chemotherapy and hormonal therapy.
• The first step in the treatment of breast cancer is to remove the cancer by surgery.
• Today, we discussed your two choices for surgical treatment. This is not a decision that I, as your doctor, can make alone. We feel it is important for you to understand a little bit about breast cancer so you can take part in deciding what is best for you.

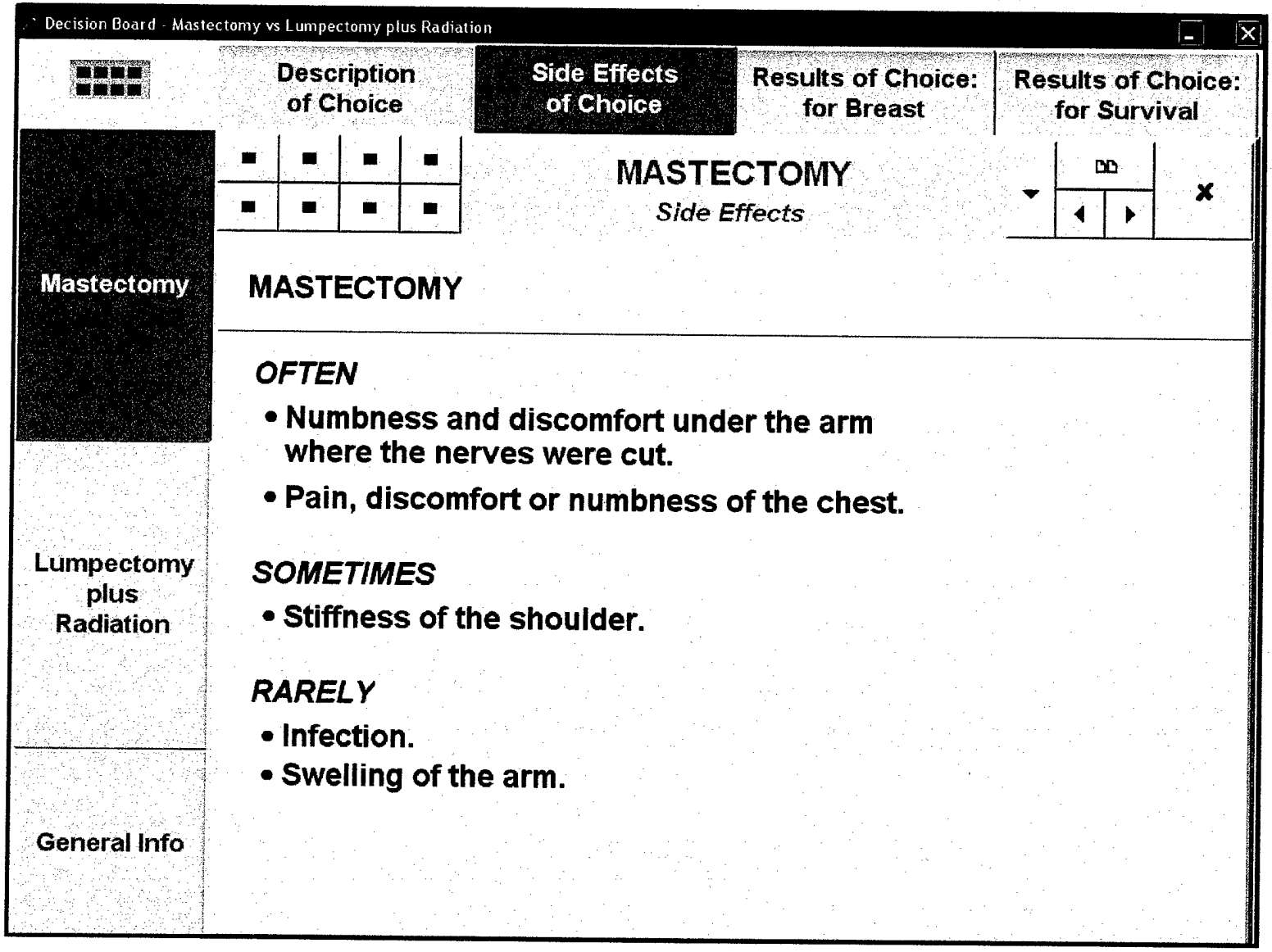

Decision Board - Mastectomy vs Lumpectomy plus Radiation
Introduction
The Decision Board
Summary
Mastectomy
Lumpectomy plus Radiation
General Info
INTRODUCTION
(2 of 3)
• Two types of surgery are possible:
one is removal of the breast, called a mastectomy;
the second is removal of the lump, called a lumpectomy.
• Since the early 1980's, the results of medical studies have shown that the two treatments are the same for survival.
In other words, one treatment is not better than the other for improving your chances of surviving cancer.
• The two treatments do differ, however.
Mastectomy results in the loss of your breast, and usually no radiation is required.
Lumpectomy, on the other hand, involves removal of the part of the breast that contains cancer, and in addition, radiation is part of the treatment.


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Introduction
The Decision Board
Summary
Mastectomy
Lumpectomy plus Radiation
General Info
INTRODUCTION
(3 of 3)
• Both of these treatments also include an axillary node dissection.
Some nodes or glands under the arm are removed at the time of surgery.
This is done to see if the cancer has spread to these nodes.
• If cancer spreads to these nodes, there is a higher chance that the cancer may spread to other parts of the body.
This is important information for you and your doctor to help decide if other treatments, such as hormonal therapy or chemotherapy, are necessary.

Decision Board - Mastectomy vs Lumpectomy plus Radiation

| | Description of Choice | Side Effects of Choice | Results of Choice: for Breast | Results of Choice: for Survival |
|---|---|---|---|---|
| **Mastectomy** | *Description* | *Side Effects* | *Results for Breast* | *Results for Survival* |
| **Lumpectomy plus Radiation** | *Description* | *Side Effects* | *Results for Breast* | *Results for Survival* |
| **General Info** | ***Introduction:*** • **Other treatments, such as hormonal therapy or chemo-therapy, may be necessary** | *The Decision Board* | | *Summary* |


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
MASTECTOMY
Description
Mastectomy
Lumpectomy plus Radiation
General Info
MASTECTOMY: Surgical Removal of the Breast
• The entire breast will be removed.
• Some lymph nodes under your arm will be removed.
• A drain is inserted near the scar under the arm for 5-10 days to remove excess fluid.
• You will come to the hospital on the day of your surgery. You will spend one night in hospital and go home the next day.
• After surgery, you may be referred to the Cancer Centre for consideration of other treatments (hormonal therapy or chemotherapy).
• Radiation is not usually necessary.


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
MASTECTOMY
Side Effects
Mastectomy
Lumpectomy plus Radiation
General Info
MASTECTOMY
OFTEN
• Numbness and discomfort under the arm where the nerves were cut.
• Pain, discomfort or numbness of the chest.
SOMETIMES
• Stiffness of the shoulder.
RARELY
• Infection.
• Swelling of the arm.

Decision Board - Mastectomy vs Lumpectomy plus Radiation

Description of Choice | Side Effects of Choice | Results of Choice: for Breast | Results of Choice: for Survival

Mastectomy

Lumpectomy plus Radiation

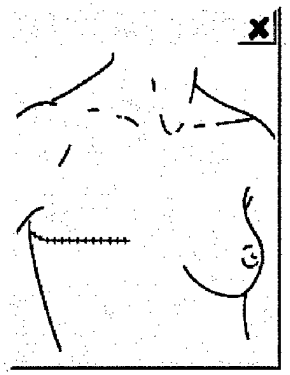
General Info

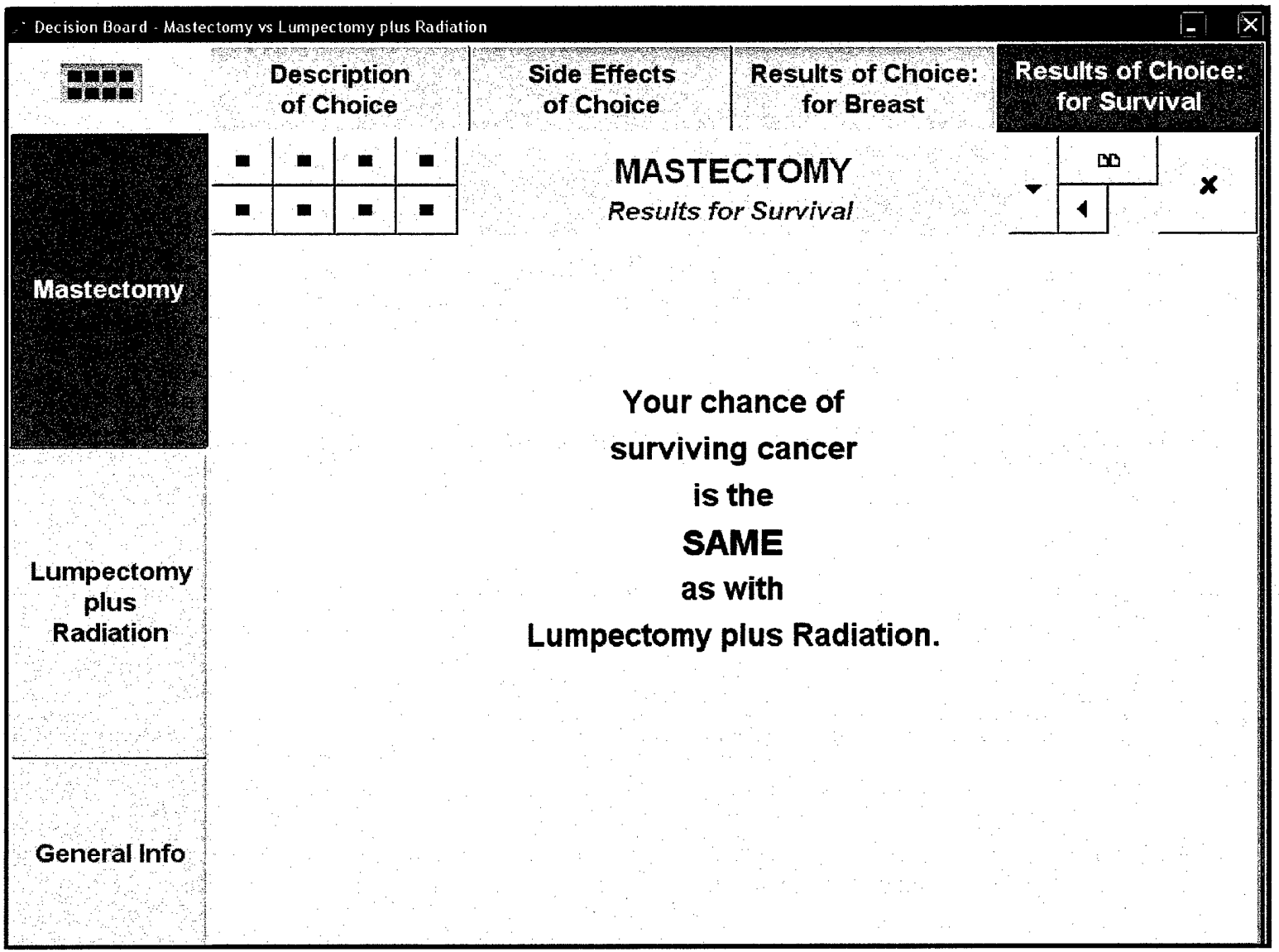
# MASTECTOMY

*Results for Breast*

## MASTECTOMY

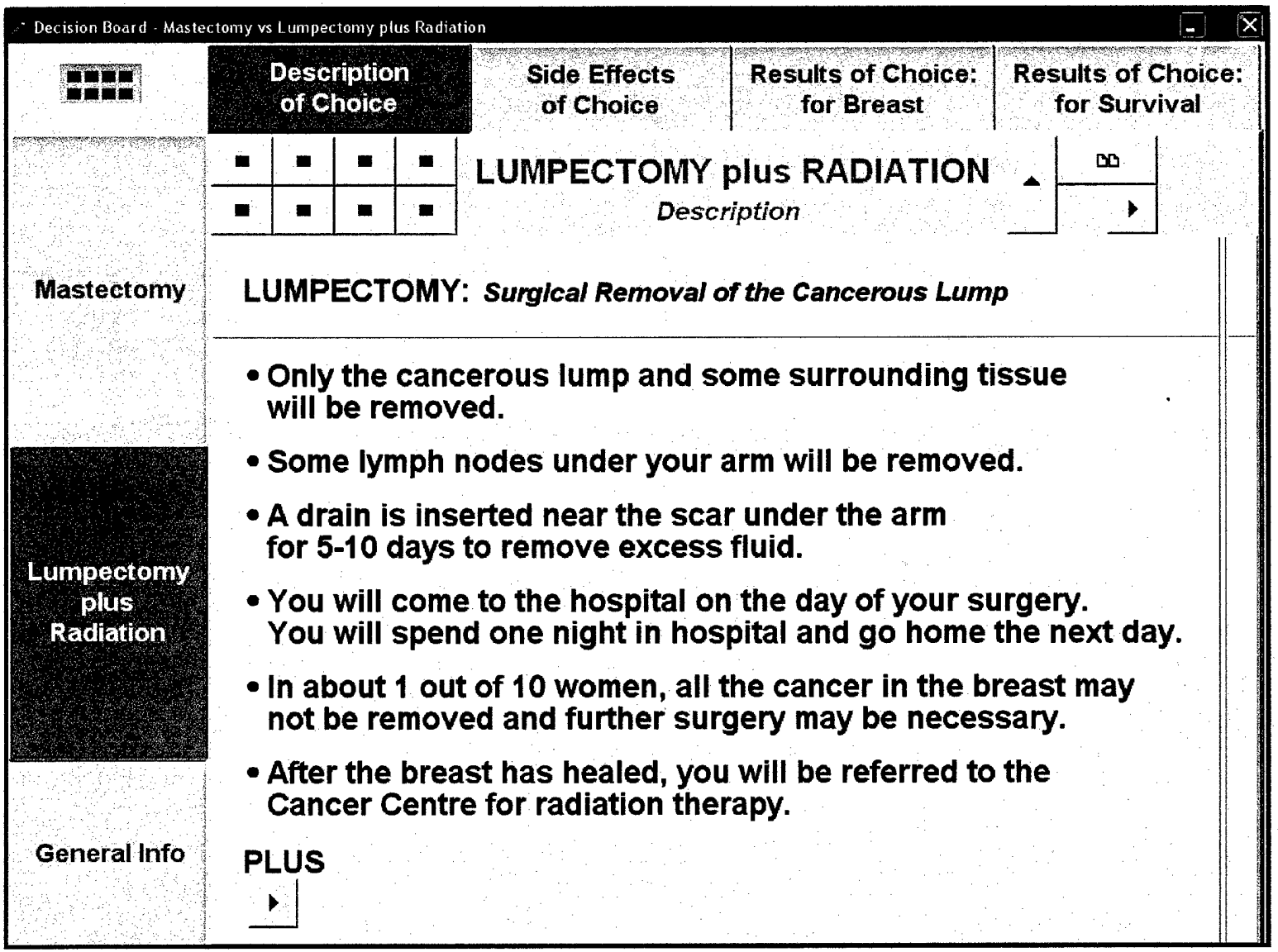
- You are left with a healed scar across your chest.
- Some women may be upset by the loss of their breast.
- A breast prosthesis or breast form can be fitted.
- The breast can be reconstructed using plastic surgery.
- Cancer may come back on the chest. About 5 to 10 out of 100 women will experience this in the next 10 years.
- Cancer that comes back on the chest is usually treated with surgery, radiation or both.

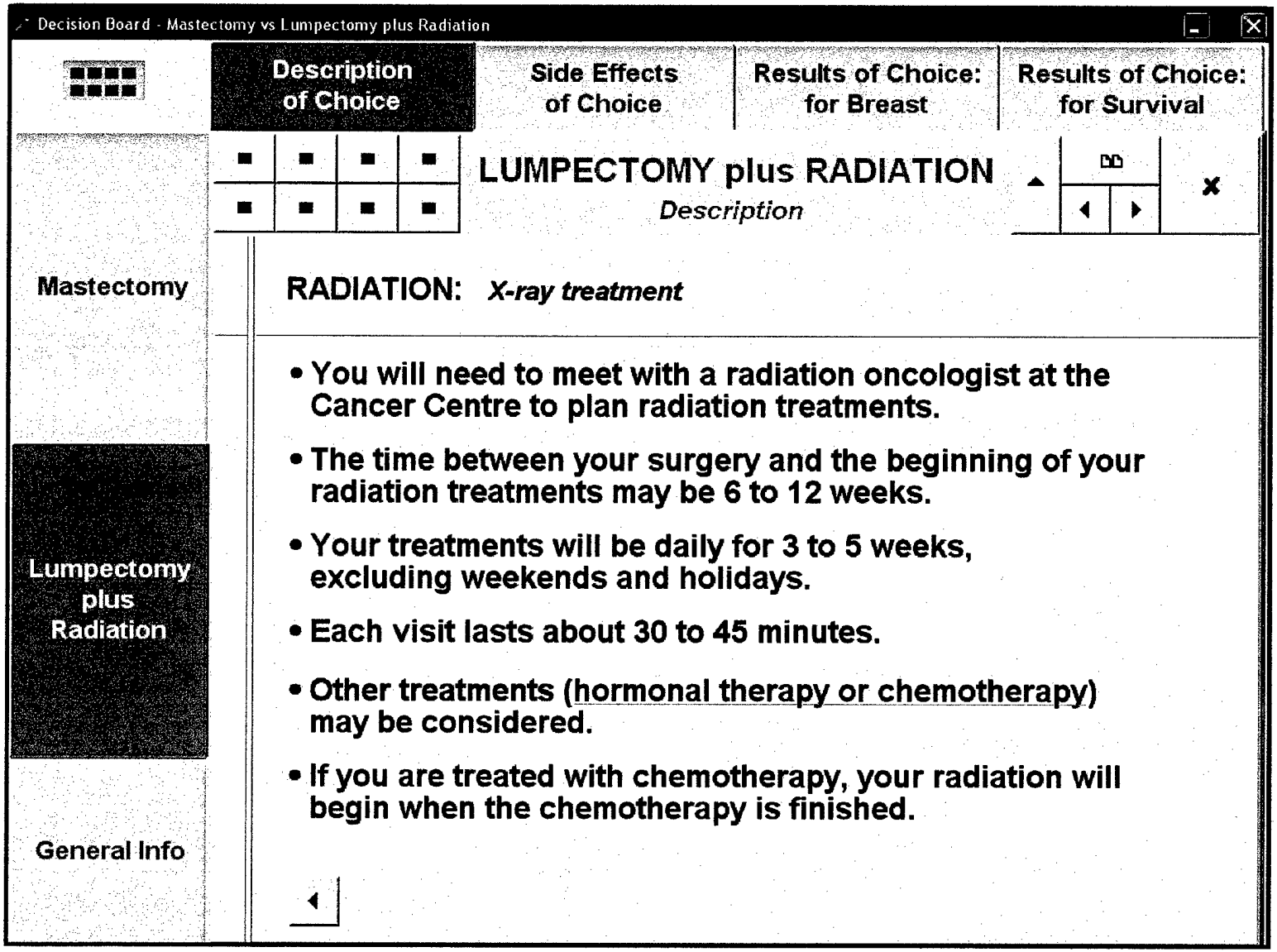


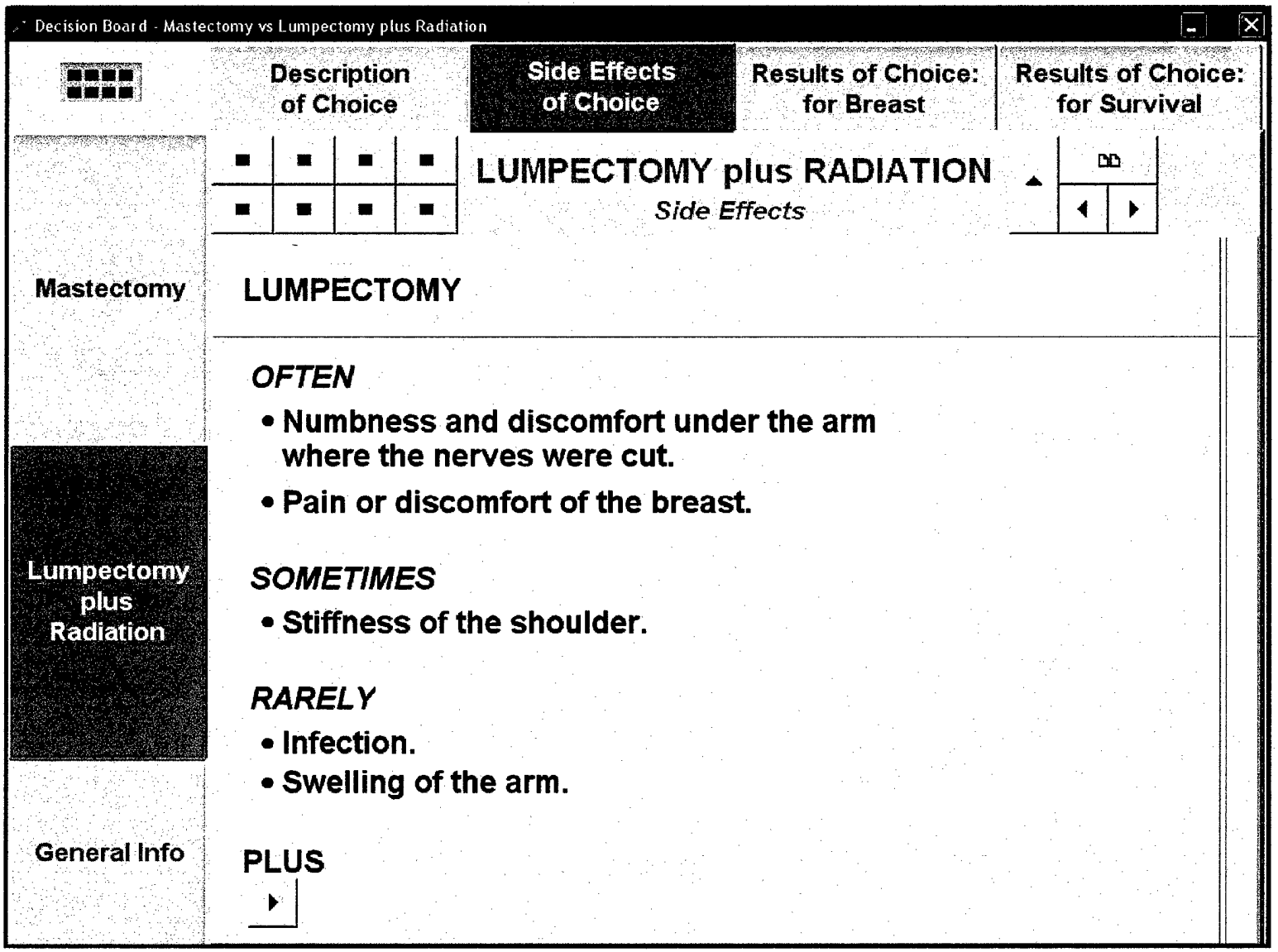

Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
MASTECTOMY
Results for Survival
Mastectomy
Lumpectomy plus Radiation
General Info
Your chance of surviving cancer is the SAME as with Lumpectomy plus Radiation.

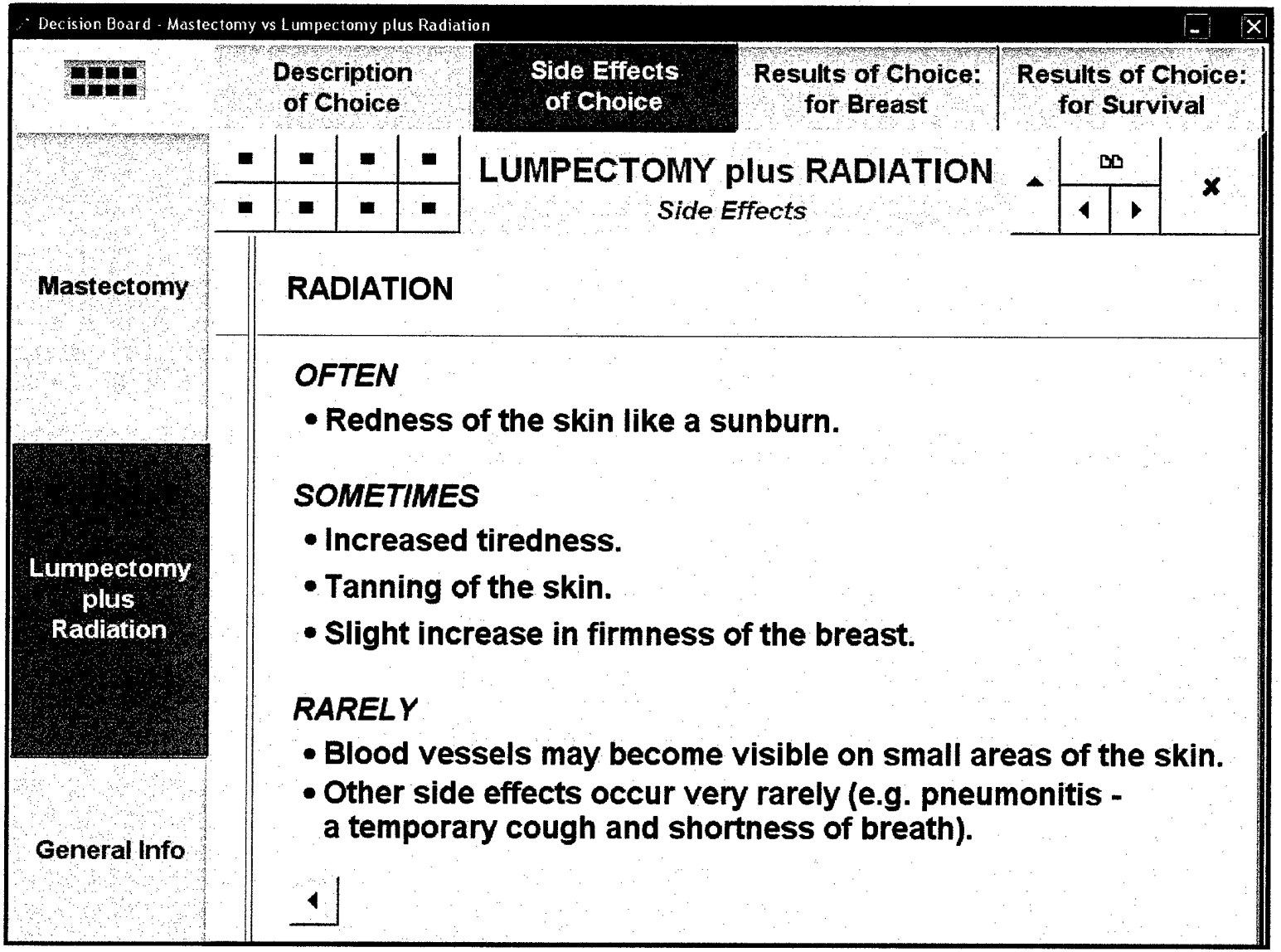
Decision Board - Mastectomy vs Lumpectomy plus Radiation

| | Description of Choice | Side Effects of Choice | Results of Choice: for Breast | Results of Choice: for Survival |
|---|---|---|---|---|
| **Mastectomy** | • Entire breast is removed<br>• Radiation is not usually necessary | • Side effects of surgery e.g. numbness, pain | • Loss of the breast<br>• Occasionally, cancer will come back | • Your chance of surviving cancer is the same as with Lumpectomy plus Radiation |
| **Lumpectomy plus Radiation** | *Description* | *Side Effects* | *Results for Breast* | *Results for Survival* |
| **General Info** | ***Introduction:***<br>• Other treatments, such as hormonal therapy or chemo-therapy, may be necessary | *The Decision Board* | *Summary* | |


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
LUMPECTOMY plus RADIATION
Description
Mastectomy
Lumpectomy plus Radiation
General Info
LUMPECTOMY: Surgical Removal of the Cancerous Lump
• Only the cancerous lump and some surrounding tissue will be removed.
• Some lymph nodes under your arm will be removed.
• A drain is inserted near the scar under the arm for 5-10 days to remove excess fluid.
• You will come to the hospital on the day of your surgery. You will spend one night in hospital and go home the next day.
• In about 1 out of 10 women, all the cancer in the breast may not be removed and further surgery may be necessary.
• After the breast has healed, you will be referred to the Cancer Centre for radiation therapy.
PLUS


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
LUMPECTOMY plus RADIATION
Description
Mastectomy
Lumpectomy plus Radiation
General Info
RADIATION: X-ray treatment
• You will need to meet with a radiation oncologist at the Cancer Centre to plan radiation treatments.
• The time between your surgery and the beginning of your radiation treatments may be 6 to 12 weeks.
• Your treatments will be daily for 3 to 5 weeks, excluding weekends and holidays.
• Each visit lasts about 30 to 45 minutes.
• Other treatments (hormonal therapy or chemotherapy) may be considered.
• If you are treated with chemotherapy, your radiation will begin when the chemotherapy is finished.


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
LUMPECTOMY plus RADIATION
Side Effects
Mastectomy
Lumpectomy plus Radiation
General Info
LUMPECTOMY
OFTEN
• Numbness and discomfort under the arm where the nerves were cut.
• Pain or discomfort of the breast.
SOMETIMES
• Stiffness of the shoulder.
RARELY
• Infection.
• Swelling of the arm.
PLUS


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
LUMPECTOMY plus RADIATION
Side Effects
Mastectomy
Lumpectomy plus Radiation
General Info
RADIATION
OFTEN
• Redness of the skin like a sunburn.
SOMETIMES
• Increased tiredness.
• Tanning of the skin.
• Slight increase in firmness of the breast.
RARELY
• Blood vessels may become visible on small areas of the skin.
• Other side effects occur very rarely (e.g. pneumonitis - a temporary cough and shortness of breath).

Decision Board - Mastectomy vs Lumpectomy plus Radiation

Description of Choice | Side Effects of Choice | Results of Choice: for Breast | Results of Choice: for Survival

Mastectomy

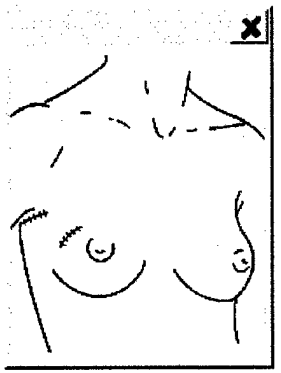
Lumpectomy plus Radiation

General Info

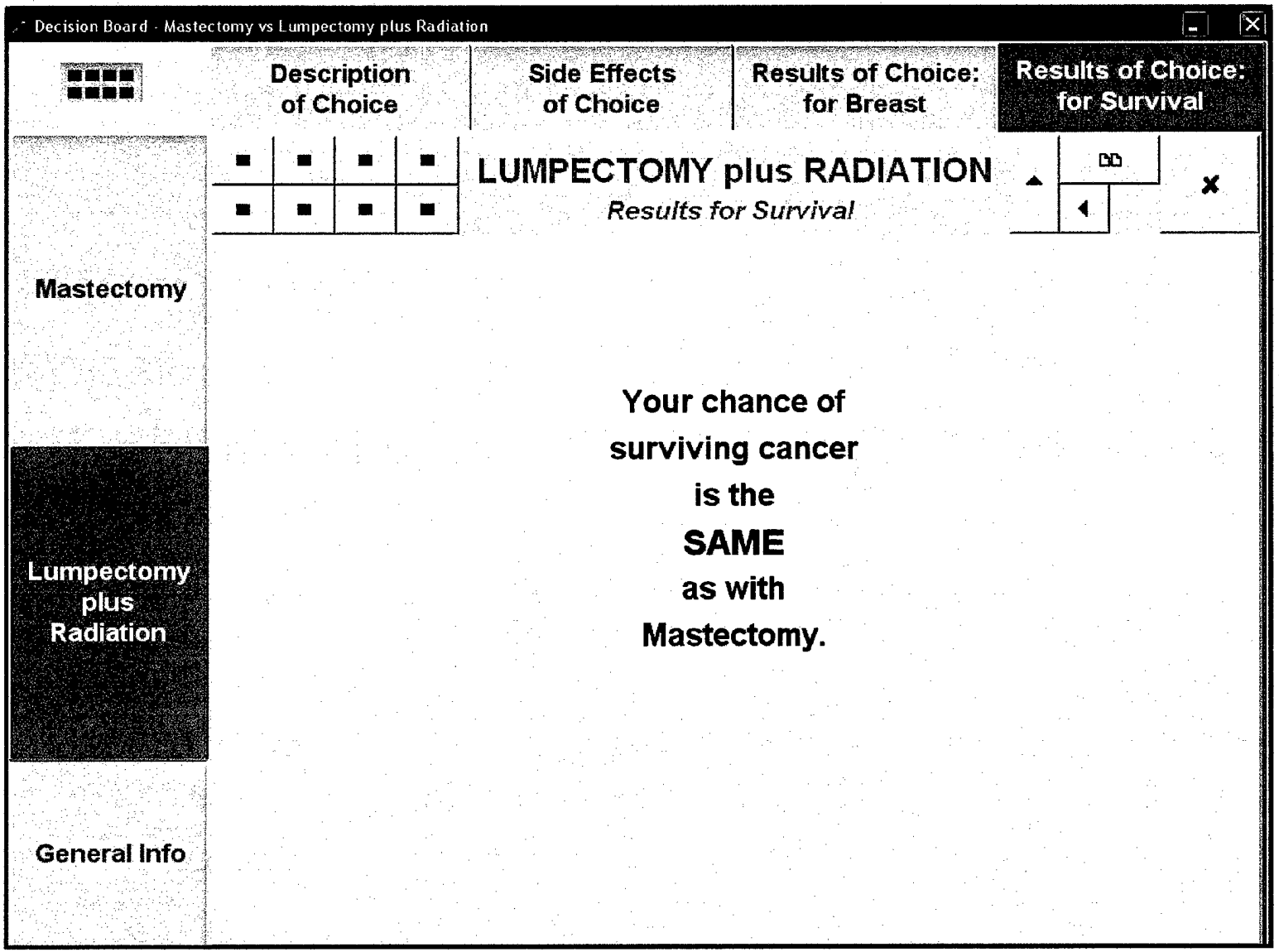
# LUMPECTOMY plus RADIATION

*Results for Breast*

## LUMPECTOMY plus RADIATION

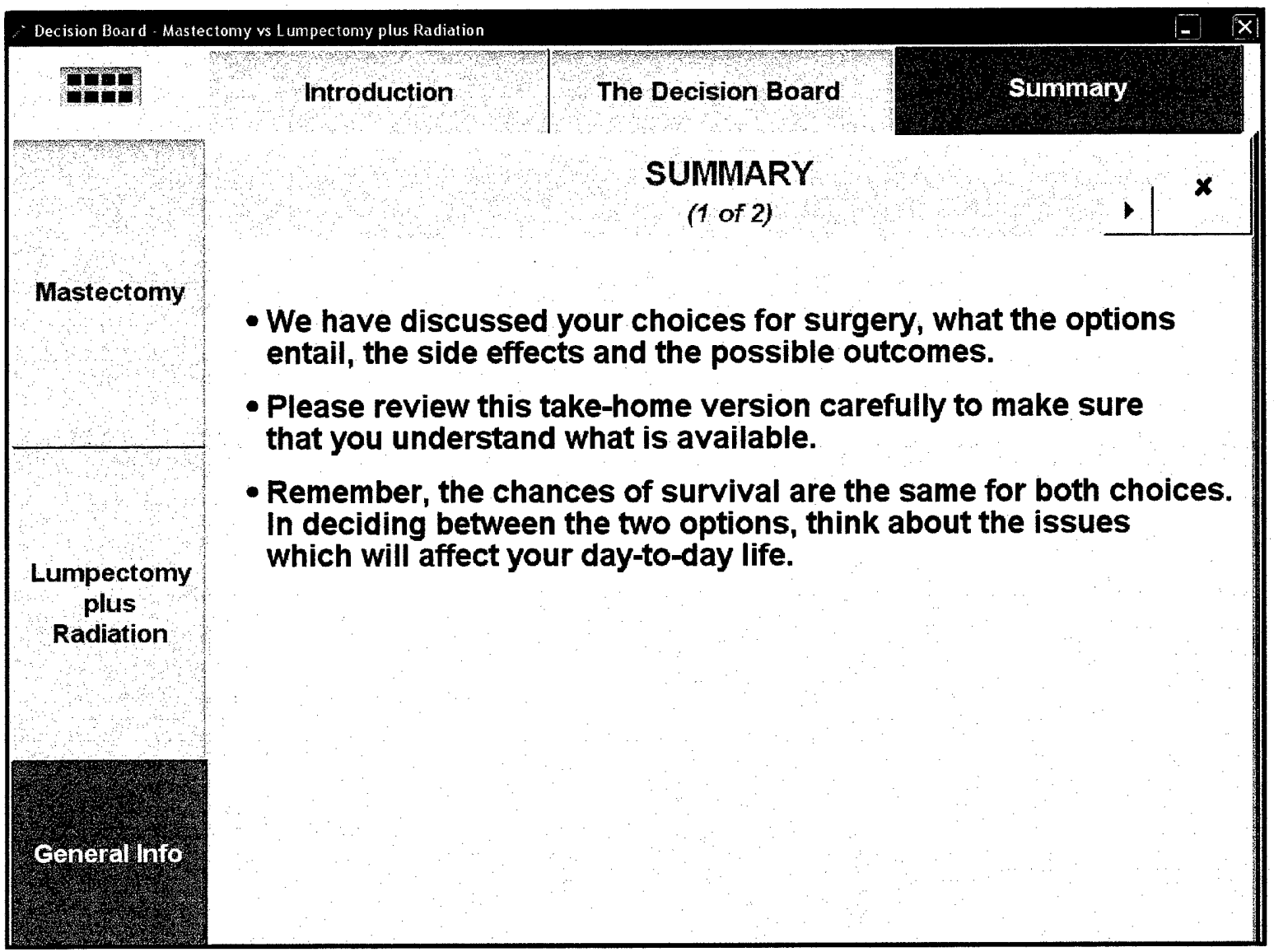


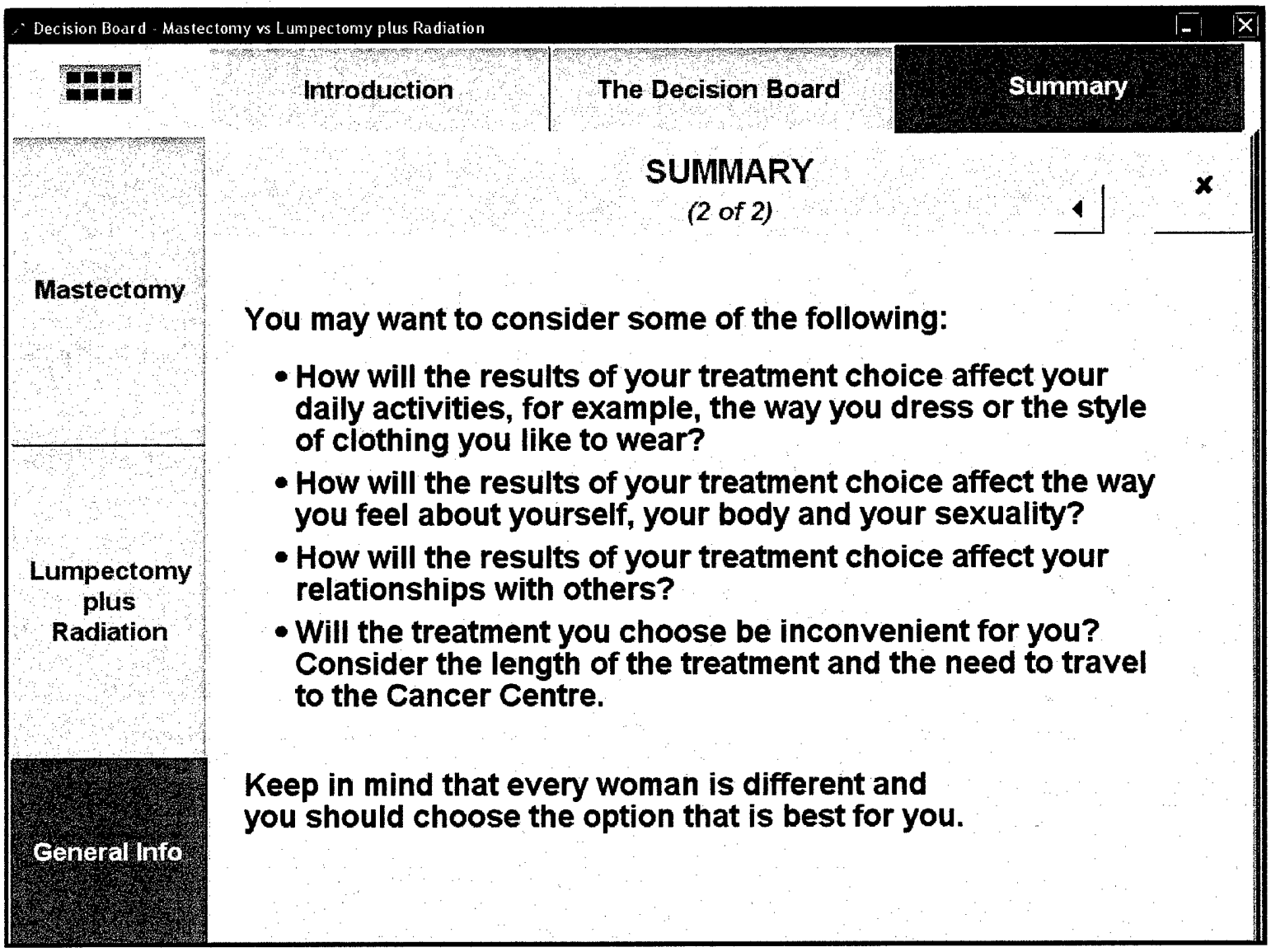
- You are left with 2 healed scars: one on the breast and one under the arm.
- There may be some indentation where the lump was removed or thickening of the breast tissue.
- Some women may be upset by the appearance of the breast, but most (8 out of 10 women) are comfortable with the way their breast looks.
- Cancer may come back in the breast. About 5 to 10 out of 100 women will experience this in the next 10 years.
- Cancer that comes back in the breast is usually removed by further surgery (lumpectomy or mastectomy). Radiation cannot be given again to the same breast.


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Description of Choice
Side Effects of Choice
Results of Choice: for Breast
Results of Choice: for Survival
LUMPECTOMY plus RADIATION
Results for Survival
Mastectomy
Lumpectomy plus Radiation
General Info
Your chance of surviving cancer is the SAME as with Mastectomy.

Decision Board - Mastectomy vs Lumpectomy plus Radiation

| | Description of Choice | Side Effects of Choice | Results of Choice: for Breast | Results of Choice: for Survival |
|---|---|---|---|---|
| Mastectomy | • Entire breast is removed<br>• Radiation is not usually necessary | • Side effects of surgery e.g. numbness, pain | • Loss of the breast<br>• Occasionally, cancer will come back | • Your chance of surviving cancer is the same as with Lumpectomy plus Radiation |
| Lumpectomy plus Radiation | • Only the cancerous lump is removed<br>• 3 to 5 weeks of radiation treatments | • Side effects of surgery e.g. numbness, pain<br>• Side effects of radiation e.g. redness of the skin | • Scar on the breast<br>• Occasionally, cancer will come back | • Your chance of surviving cancer is the same as with Mastectomy |
| General Info | *Introduction:*<br>• Other treatments, such as hormonal therapy or chemo-therapy, may be necessary | *The Decision Board* | *Summary* | |


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Introduction
The Decision Board
Summary
Mastectomy
Lumpectomy plus Radiation
General Info
SUMMARY
(1 of 2)
• We have discussed your choices for surgery, what the options entail, the side effects and the possible outcomes.
• Please review this take-home version carefully to make sure that you understand what is available.
• Remember, the chances of survival are the same for both choices. In deciding between the two options, think about the issues which will affect your day-to-day life.


Decision Board - Mastectomy vs Lumpectomy plus Radiation
Introduction
The Decision Board
Summary
Mastectomy
Lumpectomy plus Radiation
General Info
SUMMARY
(2 of 2)
You may want to consider some of the following:
• How will the results of your treatment choice affect your daily activities, for example, the way you dress or the style of clothing you like to wear?
• How will the results of your treatment choice affect the way you feel about yourself, your body and your sexuality?
• How will the results of your treatment choice affect your relationships with others?
• Will the treatment you choose be inconvenient for you? Consider the length of the treatment and the need to travel to the Cancer Centre.
Keep in mind that every woman is different and you should choose the option that is best for you.

# Appendix 6

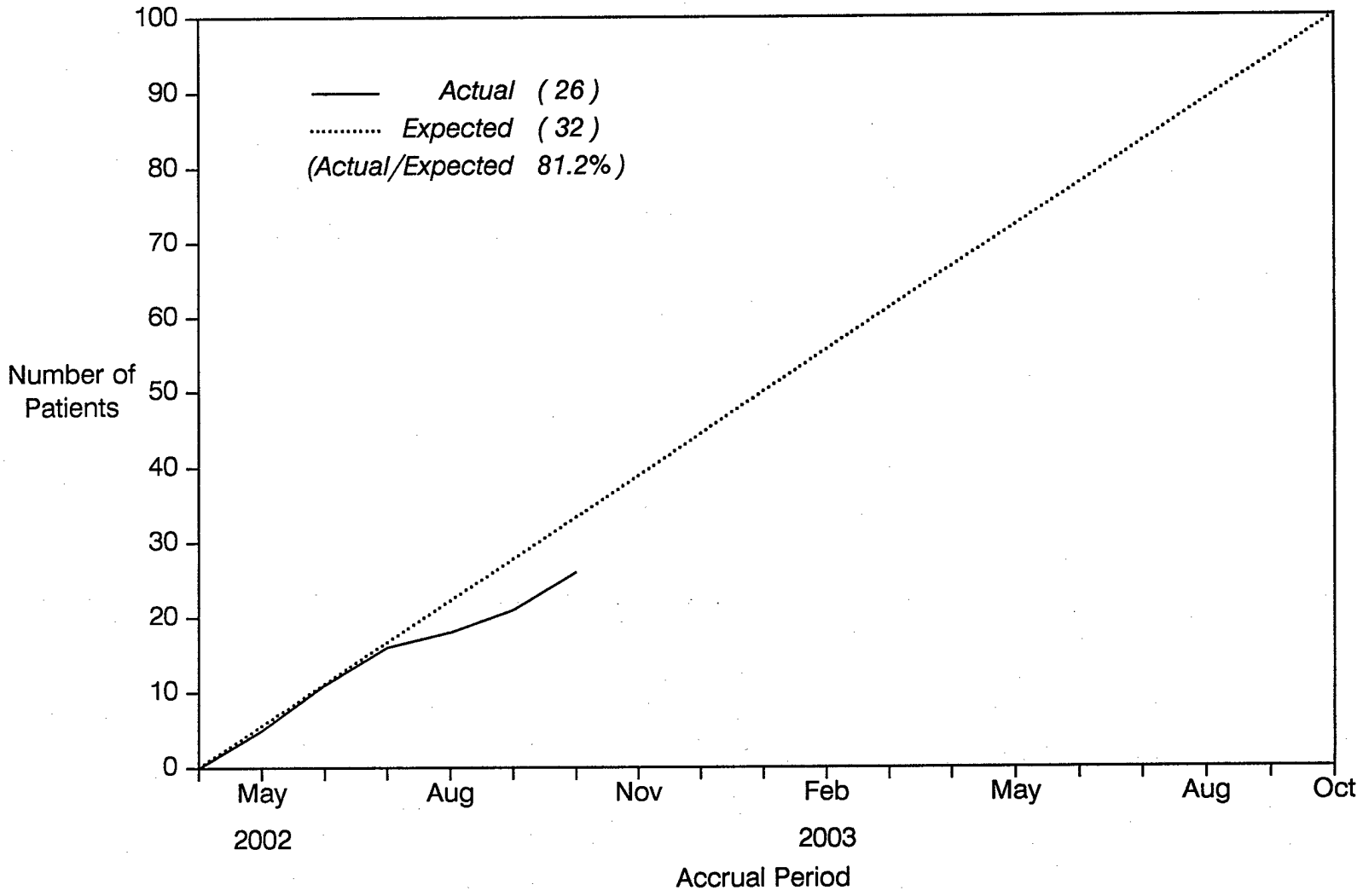
## Trial Management Reports

*(Accrual Graph,*
*Accrual Table,*
*Patient Assessment Summary*
*Overdue Assessments,*
*Follow-up Schedule by Target Date)*

# Evaluation of Different Versions of the Decision Board (DECIDE-C)

PATIENT ACCRUAL as of 28 Oct 2002

Study Started April 29, 2002 Projected Sample Size: 100 Patients in 18 Months



# Evaluation of Different Versions of the Decision Board (DECIDE-C)

## Patient Accrual by Clinical Centre, as of 28 Oct 2002

| Clinical Centre | Accrual Period | | | | | | | | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 2002 May | Jun | Jul | Aug | Sep | Oct | |
| Hamilton Regional Cancer Centre | | | | | | | | 5 | 6 | 5 | 2 | 3 | 5 | 26 |
| Total | | | | | | | | 5 | 6 | 5 | 2 | 3 | 5 | 26 |

# Evaluation of Different Versions of the Decision Board (DECIDE-C)

## Patient Assessment Summary

## as of 28 Oct 2002

| Assessment | Completed | | Pending | | Overdue | | Missed | | Total |
|---|---|---|---|---|---|---|---|---|---|
| | count | % | count | % | count | % | count | % | |
| Baseline Assessment | 26 | 100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 26 |
| 1 Week Assessment | 23 | 100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 23 |
| 3 Month Assessment | 13 | 92.9 | 0 | 0.0 | 1 | 7.1 | 0 | 0.0 | 14 |
| 6 Month Assessment | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 |

# Evaluation of Different Versions of the Decision Board (DECIDE-C)

## List of Overdue Assessments
## as of 28 Oct 2002

**Centre:** Hamilton Regional Cancer Centre

| Patient Study ID | Patient Initials | Projected Assessment Date | Assessment |
|---|---|---|---|
| 1013 | Y H | 09 Oct 2002 | 3 Month Assessment |

# Evaluation of Different Versions of the Decision Board (DECIDE-C)

## Projected Follow-up Schedule, by Target Date
## for 01 Oct 2002 - 30 Nov 2002

**Centre:** Hamilton Regional Cancer Centre

| PATIENT STUDY ID | PATIENT INITIALS | ASSESSMENT | TARGET DATE |
|---|---|---|---|
| 1013 | Y H | 3 Month Assessment | 09 Oct 2002 |
| 1016 | S J | 3 Month Assessment | 29 Oct 2002 |
| 1025 | N D | 1 Week Assessment | 04 Nov 2002 |
| 1026 | L B | 1 Week Assessment | 04 Nov 2002 |
| 1001 | J N | 6 Month Assessment | 08 Nov 2002 |
| 1002 | C R | 6 Month Assessment | 10 Nov 2002 |
| 1017 | J W | 3 Month Assessment | 19 Nov 2002 |
| 1003 | G L | 6 Month Assessment | 21 Nov 2002 |
| 1004 | F C | 6 Month Assessment | 28 Nov 2002 |
| 1018 | M B | 3 Month Assessment | 28 Nov 2002 |

10 visits